Exhibit A

CYMBALTA WITHDRAWAL PERSONAL INJURY CASES

The following are the cases that are the subject of this motion to centralize in the Southern District of Indiana. These cases are all personal injury cases involving Cymbalta withdrawal that are in the very preliminary stages of litigation across the country.

Filed & Served:

1. Ali v. Eli Lilly & Co., 14-cv-01615 (E.D. Va.)
2. Barrett v. Eli Lilly & Co., 14-cv-01675 (C.D. Cal.)
3. Boling v. Eli Lilly & Co., 14-cv-02554 (D. Md.)
4. Brotherton v. Eli Lilly & Co., 14-cv-02876 (M.D. Fla.)
5. Caporale v. Eli Lilly & Co., 14-cv-01662 (C.D. Cal.)
6. Carpenter v. Eli Lilly & Co., 14-cv-540 (D.N.H.)
7. Cheney v. Eli Lilly & Co., 14-cv-02249 (D. Colo.)
8. Cheshier v. Eli Lilly & Co., 14-cv-01265 (E.D. Cal.)
9. Couch v. Eli Lilly & Co., 14-cv-02564 (N.D. Ga.)
10. Edens v. Eli Lilly & Co., 14-cv-00491 (E.D. Tenn.)
11. Fairbanks v. Eli Lilly & Co., 14-cv-02469 (W.D. La.)
12. Gentry v. Eli Lilly & Co., 15-cv-00023 (D. Nev.)
13. Gollin v. Eli Lilly & Co., 14-cv-61810 (S.D. Fla.)
14. Hagan-Brown v. Eli Lilly & Co., 14-cv-01614 (E.D. Va.)
15. Harris v. Eli Lilly & Co., 14-cv-00682 (M.D.N.C.)
16. Hollowell v. Eli Lilly & Co., 14-cv-01663 (C.D. Cal.)
17. Kaplan v. Eli Lilly & Co., 14-cv-02752 (W.D. Tenn.)
18. Kelly v. Eli Lilly & Co., 14-cv-03869 (N.D. Cal.)
19. Krupp v. Eli Lilly & Co., 14-cv-02792 (M.D. Fla.)
20. Laica-Bhoge v. Eli Lilly & Co., 14-cv-01286 (M.D. Fla.)
21. Loux v. Eli Lilly & Co., 14-cv-01287 (D. Or.)
22. Martin v. Eli Lilly & Co., 14-cv-02800 (D. Colo.)
23. Mayes v. Eli Lilly & Co., 14-cv-01759 (N.D. Ohio.)
24. McCabe v. Eli Lilly & Co., 14-cv-03132 (D. Minn.)
25. O'Shea v. Eli Lilly & Co., 14-01274 (C.D. Cal.)
26. Patterson v. Eli Lilly & Co., 14-cv-08527 (C.D. Cal.)
27. Pickaree v. Eli Lilly & Co., 14-cv-3481 (S.D. Tex.)
28. Pokorny v. Eli Lilly & Co., 14-cv-2960 (S.D. Tex.)
29. Rossero v. Eli Lilly & Co., 14-01084 (W.D. Penn.)
30. Schaffer v. Eli Lilly & Co., 14-cv-01483 (E.D. Mo.)
31. Scherer v. Eli Lilly & Co., 14-cv-01484 (E.D. Mo.)
32. Streeter v. Eli Lilly & Co., 14-cv-00555 (W.D. Wisc.)
33. Valentino v. Eli Lilly & Co., 14-cv-01816 (M.D. Fla.)
34. Wagner v. Eli Lilly & Co., 14-cv-00270 (E.D. Wash.)
35. Walker v. Eli Lilly & Co., 14-cv-01988 (D. Nev.)
36. Wheeler v. Eli Lilly & Co., 14-01882 (S.D. Cal.)
37. Whitworth v. Eli Lilly & Co., 14-cv-00459 (E.D.N.C.)
38. Williams v. Eli Lilly & Co., 14-cv-00460 (E.D.N.C.)

39. Woodruff v. Eli Lilly & Co., 14-cv-01890 (E.D. Cal.)

Filed & Not Served:

40. Ben v. Eli Lilly & Co., 14-cv-02914 (E.D. Cal.)
41. Moss v. Eli Lilly & Co., 14-cv-01135 (M.D. Ala.)
42. Nelson-Devlin v. Eli Lilly & Co., 14-cv-02811 (E.D. Cal.)
43. Orlando v. Eli Lilly & Co., 14-cv-00438 (D. Me.)
44. Spearman v. Eli Lilly & Co., 15-cv-00006 (N.D. Miss.)
45. Wolff v. Eli Lilly & Co., 14-cv-03004 (E.D. Cal.)
46. Lemley v. Eli Lilly & Co., 14-cv-02097 (N.D. Ala.)

Cases in the Southern District of Indiana as of 2/11/2015:

47. Hill v. Eli Lilly & Co., 15-cv-00141 (S.D. Ind.)

Exhibit B

BEFORE THE UNITED STATES JUDICIAL PANEL
ON MULTIDISTRICT LITIGATION

In re: Cymbalta Products Liability Litigation MDL Docket No. _____

MEMORANDUM IN SUPPORT OF PLAINTIFFS' MOTION PURSUANT TO 28 U.S.C. § 1407 TO TRANSFER RELATED ACTIONS FOR COORDINATED PRETRIAL PROCEEDINGS IN THE CENTRAL DISTRICT OF CALIFORNIA

The Plaintiffs[1] (hereafter "Movants"), respectfully submit this memorandum of law in support of Plaintiffs' motion, pursuant to 28 U.S.C. § 1407, to centralize twenty-eight related federal actions, and any subsequently filed related actions, in the Central District of California before the Honorable Stephen V. Wilson or Honorable George H. King for coordinated pretrial proceedings. The related actions allege product liability claims against Defendant Eli Lilly and Company ("Lilly") for injuries caused by the use and discontinuation of the prescription drug Cymbalta (also known as duloxetine), i.e., "Cymbalta Withdrawal."

PRELIMINARY STATEMENT

Movants request coordination of these related Cymbalta withdrawal actions in a Multidistrict Litigation ("MDL") because: (i) the actions assert product liability claims against Lilly for injuries sustained by people discontinuing Cymbalta; (ii) the actions involve common questions of fact, including Cymbalta's capacity to cause withdrawal injuries and whether Lilly properly warned about the risks of Cymbalta withdrawal; (iii) transfer to a single district will be convenient for all parties and witnesses and will allow for just and efficient pretrial proceedings; and (iv) absent transfer and coordination, the parties and courts will face the burden and expense of duplicative discovery and pretrial proceedings and inconsistent pretrial rulings.

[1] Thomas Seagroves and Ute Seagroves, Sidney Carter, Erin Hexum and Nick Hexum, Claudia Herrera and Peter Lowry, Jesse McDowell, Veronica Lister, Peggy Barrett and Roger Barrett, Deborah Caporale and George Caporale, Anita Hollowell and Edward Hollowell, Kerry O'Shea and Sharlene O'Shea, Deanna Cheshier Carl Woodruff and Penny Woodruff, Elisa Wheeler and James Wheeler, Kelly Cheney, Heather Laica-Bhoge and Alberto Bhoge, Douglas Gollin and Lynn Gollin, Sandra Couch, Johnson Fairbanks, Karen Boling and Joseph Boling, Eric McCabe, Shelly Harris, Elizabeth Whitworth, Mark Williams, Gregory Mayes, Donna Loux, Melissa Rossero, Karen Wagner, and Adam Streeter.

The creation of an MDL for Cymbalta Withdrawal cases is appropriate because there are currently twenty-eight actions pending before twenty-two district courts and twenty-one federal district judges, each of which is in the pretrial stages of litigation. Moreover, undersigned Plaintiffs' counsel anticipates that there will be many additional Cymbalta Withdrawal cases filed in the future. Indeed, given that the alleged withdrawal injuries at issue here affect at least 44-50% of Cymbalta consumers,[2] it is likely that many hundreds of cases will be filed during the course of this litigation. This expected volume alone warrants an MDL.

In addition, Plaintiffs request that the MDL be centralized in the Central District of California before the Honorable Stephen V. Wilson or the Honorable George H. King. The Central District of California has a robust record with MDLs, including those involving pharmaceutical drugs, is in a highly accessible district in a metropolitan location, has the requisite resources and expertise to manage such an MDL, and has specific experience dealing with antidepressant withdrawal litigation, *see In re Paxil Prods. Liab. Litig.*, Case No.: 03-ML-1574 (C.D. Cal.) (J. Pfaelzer); *In re Paxil Products Liab. Litig.*, 296 F. Supp. 2d 1374, 1375 (J.P.M.L. 2003) (order centralizing Paxil withdrawal litigation in Central District of California)[3]

Since October 2012, Judge Wilson has been overseeing *Saavedra v. Eli Lilly & Co.*, Case No.: 2:12-cv-09366, (C.D. Cal.), a class action based on consumer protection law and the first case filed in federal court related to Cymbalta Withdrawal. Judge Wilson has developed significant familiarity with this litigation and has already issued several pretrial orders relating to important issues such as the learned intermediary doctrine and federal preemption. Moreover,

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[2] *See* David G. Perahia et al., *Symptoms Following Abrupt Discontinuation of Duloxetine Treatment in Patients with Major Depressive Disorder*, 89 J. AFFECTIVE DISORDERS 207-212, 208-09 (2005) (indicating that approximately 51% of patients who *knowingly* stopped taking Cymbalta experienced withdrawal symptoms); *see also* Joseph Glenmullen, M.D., *The Antidepressant Solution: A Step-by-Step Guide to Safely Overcoming Antidepressant Withdrawal, Dependence and "Addiction,"* p. 83-84 (based on Cymbalta's half-life, the frequency of withdrawal reactions is more likely between 66% and 78%).

[3] Over 3000 cases were filed in the *In re Paxil* MDL.

the issue of class certification is fully briefed and has been under submission for several months. Similarly, California Central District Chief Judge King is familiar with Cymbalta withdrawal cases, as he has been presiding over three personal injury cases that are in the midst of pretrial discovery: *Carter v. Eli Lilly and Company*, 13-CV-2700 GHK (FFMx) (C.D. Cal.); *Hexum v. Eli Lilly and Company*, 13-CV-2701 GHK (FFMx) (C.D. Cal.); *Herrera v. Eli Lilly and Compan*y, 13-CV-2702 GHK (FFMx). Pretrial coordination before either Judge Wilson or Judge King would be appropriate and would further the goals and purposes of centralization under 28 U.S.C. § 1407.

STATEMENT OF FACTS

Lilly is one of the largest pharmaceutical companies in the world with annual revenues exceeding $22 billion. A substantial portion of Lilly's sales and profits were derived from its drug Cymbalta, whose 2012 annual sales approached $5 billion, making it the most profitable drug in Lilly's product line before going generic in 2013.

Lilly has long enjoyed considerable financial success from manufacturing and selling prescription antidepressant drugs, including the popular antidepressant, Prozac, which was introduced in the United State market in 1987. While marketing Prozac, Lilly pioneered research on the withdrawal effects of antidepressant medications. Prozac, unlike its early competitors Paxil and Zoloft, has a very long half-life (i.e., the time it takes for half of the drug to leave a patient's body). Lilly suggested that the longer it takes for a drug to leave a patient's system, the less risk there is of suffering from withdrawal symptoms because there is a gradual decrease of the drug's plasma concentration. Lilly used Prozac's long half-life to position Prozac as being superior to Paxil and Zoloft because Prozac posed significantly less risk of withdrawal syndrome.

In 2001, Lilly filled the void left behind by Prozac's patent expiration by seeking approval from the Food and Drug Administration ("FDA") for its next antidepressant, Cymbalta. Cymbalta is a "Serotonin-Norepinephrine Reuptake Inhibitor" ("SNRI"), which Lilly promoted as increasing the brain chemicals serotonin and norepinephrine in the synaptic clefts between the neurons in the brain. Lilly and other SNRI manufacturers admit that the precise mechanism of action is not clear, however, they have promoted the drugs by stating that higher levels of these neurotransmitters somehow improve and elevate mood.

In 2003, the FDA initially rejected Lilly's application to approve Cymbalta due to certain violations of good manufacturing practices and the risk of liver toxicity apparent in the drug's safety profile. Eventually, in 2004, manufacturing issues were resolved and the FDA approved Cymbalta for Major Depressive Disorder ("MDD") with a liver toxicity warning included in the prescribing information. In 2007, the FDA approved Cymbalta for treatment of Generalized Anxiety Disorder ("GAD") and, in 2008, for treatment of fibromyalgia.

Since the FDA's initial approval of Cymbalta in 2004, Lilly has aggressively marketed the drug to the public and the medical community, spending hundreds of millions of dollars each year on advertising and promotion. Lilly promoted Cymbalta directly to consumers through all major media channels, including internet, print media, and television. In addition, Lilly promoted Cymbalta to the medical community by utilizing its well-organized army of sales representatives to personally visit physicians and health care professionals to distribute free drug samples and promotional literature. Lilly further promoted Cymbalta through advertisements in medical journals and presenting talks and exhibits at medical conferences.

Lilly has continuously overstated the efficacy of Cymbalta and understated, downplayed, and/or failed altogether to state the true withdrawal side effects associated with Cymbalta. The

Cymbalta label concerning withdrawal states:

> Discontinuation symptoms have been systematically evaluated in patients taking duloxetine. Following abrupt or tapered discontinuation in placebo-controlled clinical trials, the following symptoms occurred at a rate **greater than or equal to 1%** and at a significantly higher rate in duloxetine-treated patients compared to those discontinuing from placebo: dizziness, nausea, headache, fatigue, paresthesia, vomiting, irritability, nightmares, insomnia, diarrhea, anxiety, hyperhidrosis and vertigo[.]

(Emphasis added).

Lilly's Cymbalta warning is grossly misleading and inadequate. In addition to using the euphemistic term "discontinuation" to describe withdrawal, the label overtly invites physicians and patients to believe that discontinuation symptoms are rare and affect only about 1% of Cymbalta users. But Lilly's own clinical trials for Cymbalta clearly show that a significant percentage (at least 44.3%) of Cymbalta patients suffered from "discontinuation" side effects when they stopped taking the medication. David G. Perahia et al., *Symptoms Following Abrupt Discontinuation of Duloxetine Treatment in Patients with Major Depressive Disorder*, 89 J. AFFECTIVE DISORDERS 207-212, 207 (2005). According to Lilly's scientists, the withdrawal rates for Cymbalta were nearly double that experienced by placebo users, and these findings were statistically significant. For those patients who knowingly took Cymbalta, 50.8% suffered withdrawal symptoms. Moreover, the study notes that these estimates are conservative because the data collected was from spontaneous reports rather than a symptoms checklist, which would "be expected to produce higher incidence rates." Accordingly, the rate of withdrawal or "discontinuation" for Cymbalta according to Lilly's own clinical trials was, at the very least, 44.3% to 50.8%. But Lilly misleadingly presented this rate as approximately 1%.[4]

[4] Additionally, Lilly's clinical trials showed that, overall, 9.6% to 17.2% of Cymbalta users suffered *severe* withdrawal side effects, yet the Cymbalta label is entirely silent on that risk. Cymbalta's withdrawal side effects include, among other things, headaches, dizziness, nausea, fatigue, diarrhea, paresthesia, vomiting, irritability, nightmares, insomnia, anxiety, hyperhidrosis, sensory disturbances, electric shock sensations, seizures and vertigo.

Notwithstanding Lilly's knowledge of the high rate of withdrawal symptoms in patients stopping Cymbalta, Lilly failed to adequately, properly, and fully warn patients and physicians about the risk. Instead, in its product labeling, marketing and advertising, and in information made available to consumers and physicians, Lilly reported a far lower risk, downplayed any difference in the withdrawal risk for Cymbalta as compared to other similar antidepressants, and affirmatively misled the consuming patient population and mischaracterized the drug's risk profile. Lilly pioneered the antidepressant research relating to withdrawal in its marketing of Prozac, so the company was well aware of the importance of the risk. Indeed, the half-life for Cymablta is approximately twelve hours, meaning it takes twelve hours for half of Cymablta to leave a patient's system. So a patient who misses only one dose (or even a patient simply in between daily doses), can begin to experience withdrawal symptoms. Lilly knew this information and knew that Cymbalta's short half-life was the second worst among antidepressant medications. But Lilly never adequately warned patients and prescribers about this risk.

In October 2012, the Institute for Safe Medication Practices ("ISMP"), a non-profit healthcare consumer safety watchdog, issued findings from its independent investigation of Cymbalta adverse events found in the FDA Adverse Event Reporting System ("FAERS"). *See* Thomas Moore et al., *Monitoring FDA MedWatch Reports, Why Reports of Serious Adverse Drug Events Continue to Grow*, QUARTERWATCH, Oct. 3, 2012, *available at* http://www.ismp.org/quarterwatch/pdfs/2012Q1.pdf. The report found a safety "signal for serious drug withdrawal symptoms associated with duloxetine (CYMBALTA)," and explained that "withdrawal symptoms were reported in 44-50% of patients abruptly discontinuing duloxetine at the end of clinical studies for depression, and more than half of this total did not resolve within a

When patients try to stop taking Cymbalta, the side effects can be severe enough to force them to start taking Cymbalta again, not to treat their underlying condition, but simply to stop the withdrawal symptoms. Indeed, some patients, according to Lilly's study, required hospitalization.

week or two." *Id.* at 11. The report stated that there was "a serious breakdown at both the FDA and the manufacturer, Eli Lilly and Company, in providing adequate warnings and instructions about how to manage this common adverse effect." *Id.* In conclusion, the report minced no words in its indictment of Lilly's product information: "A major lapse has occurred in the FDA-approved information for patients about the risks of stopping duloxetine." *Id.* at 15.

Numerous lawsuits have been filed against Lilly alleging injuries caused by the withdrawal effects of Cymbalta, including those listed in the accompanying Schedule of Actions. These lawsuits allege that Lilly failed to warn patients and prescribers adequately about the risks of suffering from withdrawal when ceasing Cymbalta. The complaints also allege that Lilly failed to provide information about how to effectively withdraw from Cymbalta. Because of these failures to warn, the complaints allege that Lilly caused patients who stopped ingesting Cymbalta to experience personal injuries and other forms of legally cognizable damages.

ARGUMENT

I. Transfer and Pretrial Coordination of These Related Cymbalta Withdrawal Cases Will Promote the Just and Efficient Conduct of Litigation and Further the Goals of 28 U.S.C. § 1407.

Transfer and pretrial coordination of these related actions in a single court is appropriate and will promote the goals of 28 U.S.C. § 1407. Transfer is appropriate where: (A) "civil actions involving one or more common questions of fact are pending in different districts"; (B) transfer and coordination "will promote the just and efficient conduct of such actions"; and (C) transfer and coordination will serve "the convenience of parties and witnesses." 28 U.S.C. § 1407(a). As set forth below, all of these criteria are satisfied here.

A. The Related Actions Involve Common Issues of Fact.

These Cymbalta Withdrawal actions share many factual issues. Each alleges that Cymbalta caused withdrawal reactions and injuries to patients who ceased ingesting Cymbalta and that

Lilly, through its labeling, advertising, and promotion, failed to adequately warn about the risk of withdrawal. This is why the plaintiffs all assert similar causes of action, including negligence, failure-to-warn, breach of warranty, fraud, and various state-specific consumer fraud claims. The actions also involve the same categories of plaintiffs—patients who stopped ingesting Cymbalta and allegedly experienced withdrawal injuries as a result—and the same defendant, Eli Lilly and Company. And, because Lilly takes the position that the Cymbalta warning label is adequate as it currently reads, significant pretrial discovery will be required to evaluate Cymbalta's propensity to induce withdrawal, Lilly's knowledge of Cymbalta's withdrawal risks, and any effort by Lilly to conceal those risks including Lilly's decision to implement, and its implementation of the "greater than or equal to 1%" labeling language—pretrial discovery that will apply equally to *all* plaintiffs.

Although these Cymbalta Withdrawal actions present certain individualized factual issues, (e.g., specific causation and damages), "Section 1407 does not require a complete identity or even a majority of common factual issues as a prerequisite to centralization." *In re Zimmer Durom Hip Cup Prods. Liab. Litig.*, 717 F. Supp. 2d 1376, 1378; (J.P.M.L. 2010); *see In re Denture Cream Prods. Liab. Litig.*, 624 F. Supp. 2d 1379, 1381 (J.P.M.L. 2009). Instead, where, as here, the underlying factual and legal allegations are sufficiently similar, "[t]ransferee judges have demonstrated the ability to accommodate common and individual discovery tracks, gaining the benefits of centralization without delaying or compromising consideration of claims on their individual merits." *In re Yamaha Motor Corp. Rhino ATV Prods. Liab. Litig.*, 597 F. Supp. 2d 1377, 1378 (J.P.M.L. 2009); see *In re: Zoloft (Sertraline Hydrochloride) Products Liab. Litig.*, MDL 2342, 2012 WL 1389649 (Apr. 17, 2012) ("[W]e have found that products liability cases often present some individual factual issues, but that coordination of discovery across all actions,

with the use of common and individual discovery tracks, can offer efficiencies to all parties.") (citing *In re Darvocet, Darvon & Propoxyphene Prods. Liab. Litig.*, 780 F. Supp. 2d 1379, 1381 (J.P.M.L. 2011)). Courts frequently apply a dual discovery approach in products liability actions involving pharmaceutical products. *See, e.g.*, *In re: Actos Products Liab. Litig.*, MDL 2299, 2011 WL 6889721 (Dec. 29, 2011); *In re: Zoloft*, 2012 WL 1389649; *In re Yasmin & Yaz (Drospirenone) Mktg., Sales Practices & Prods. Liab. Litig.*, 655 F. Supp. 2d 1343, 1344 (J.P.M.L. 2009); *In re Chantix (Varenicline) Prods. Liab. Litig.*, 655 F. Supp. 2d 1346, 1346 (J.P.M.L. 2009); *In re Vioxx Prods. Liab. Litig.*, 360 F. Supp. 2d 1352, 1354 (J.P.M.L. 2005). "The transferee judge also can use any number of pretrial techniques, such as plaintiff fact sheets and separate motion tracks, to resolve threshold issues promptly." *In re Darvocet*, 780 F. Supp. 2d at 1381. Indeed, this litigation approach was successfully applied to similar injuries arising from withdrawal from the antidepressant Paxil. *See In re Paxil*, 296 F. Supp. 2d at 1375.

B. Coordination Promotes the Just and Efficient Management of Pretrial Proceedings for All Related Actions.

Because these related Cymbalta Withdrawal actions share common questions of fact and implicate overlapping fact and expert discovery, coordination of these actions before a single judge will provide the most efficient approach to managing the cases at this time.

In each of the twenty-eight pending actions, the Plaintiffs are likely to seek much of the same discovery from Lilly, including documents and deposition testimony related to the testing, design, labeling, marketing, and safety of Cymbalta and Lilly's research and evaluation of antidepressant withdrawal for other products like Prozac. Coordinating the actions before one judge allows the parties and the court to address this overlapping discovery in an organized manner and avoid the costly duplication of efforts and judicial resources that would be required if the cases proceeded on separate schedules and in separate courts. This Panel consistently

recognizes that Section 1407 coordination is a preferred way to manage individual lawsuits that raise similar questions regarding a defendant's development, design, and testing of a particular prescription medication or device. *See, e.g.*, *In re Zyprexa Prods. Liab. Litig.*, 314 F. Supp. 2d 1380, 1381-82 (J.P.M.L. 2004); *In re Prempro Prods. Liab. Litig.*, 254 F. Supp. 2d 1366, 1367 (J.P.M.L. 2003); *In re Temporomandibular Joint (TMJ) Implants Prods. Liab. Litig.*, 844 F. Supp. 1553, 1554 (J.P.M.L. 1994); *In re Silicone Gel Breast Implants Prods. Liab. Litig.*, 793 F. Supp. 1098, 1100 (J.P.M.L. 1992); *In re A. H. Robins Co. "Dalkon Shield" IUD Prods. Liab. Litig.*, 406 F. Supp. 540, 542 (J.P.M.L. 1975).

Coordination is also appropriate to avoid potentially inconsistent pre-trial rulings on the same or similar issues, including expert challenges under *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), and the uncertainty and confusion that would result. *See In re Zimmer Nexgen Knee Implant Prods. Liab. Litig.*, MDL No. 2272, 2011 WL 3563293, at *1 (J.P.M.L. Aug. 8, 2011) ("Centralization under Section 1407 will eliminate duplicative discovery, [and] prevent inconsistent pretrial rulings on *Daubert* and other pretrial issues . . . ."); *In re Transocean Tender Offer Sec. Litig.*, 415 F. Supp. 382, 384 (J.P.M.L. 1976) ("[T]he likelihood of motions for partial dismissal and summary judgment in all three actions grounded at least in part on [a common issue] makes Section 1407 treatment additionally necessary to prevent conflicting pretrial rulings and conserve judicial effort."). By way of example, in the ongoing litigation in the *Carter*, *Herrera*, and *Hexum* cases, there is a discovery dispute about whether the plaintiffs are entitled to discovery from Lilly relating to the company's research into Prozac withdrawal and the company's understanding of how antidepressant withdrawal impacts sales and marketing. Resolution of this hotly contested issue—an issue that could impact many cases—should be resolved by a single judge in a single court. Allowing this pretrial issue to be

resolved by different courts in different jurisdictions could result in conflicting and inconsistent pretrial rulings.

It should also be noted that this proposed MDL will likely involve many hundreds, if not thousands, of cases and that, absent centralization and coordination, this blossoming litigation will become untenable and inefficient. Lilly's clinical trials indicate that as at least 44% to 50% of Cymbalta users experience withdrawal. This means that the potential number of individuals who suffered withdrawal effects and, thus, have a claim, number in the millions. A simple search of "Cymbalta Withdrawal" on the internet reveals that there is a large online community of people who have suffered from the withdrawal effects of Cymbalta.[5] Although this petition only identifies twenty-eight cases for transfer, this MDL is expected to balloon quickly. Undersigned counsel's experience as lead MDL counsel in *In re Paxil* confirms as much. In *In re Paxil*, which also involved withdrawal injuries associated with an antidepressant, the initial MDL petition only involved twelve actions. 296 F. Supp. 2d at 1374. However, the MDL quickly expanded to include over 3,000 claims. Absent centralization, coherent litigation of these cases would have been impossible and grossly inefficient. The same rationale applies here. Many hundreds of Cymbalta Withdrawal cases are in the pipeline and, unless an MDL is created to coordinate these actions, the litigation will become needlessly chaotic and untenable.

C. Coordination Will Serve the Convenience of Witnesses and Parties.

For many of the same reasons that coordination will promote the just and efficient management of the actions at this time, it will also serve the convenience of the witnesses and parties. In particular, coordinating and streamlining discovery will minimize unnecessary duplication, travel, and other expenses, and allow the parties to conserve, and more effectively

[5] Indeed, one of Plaintiffs' firms has reviewed or is reviewing thousands of potential cases related to Cymbalta Withdrawal and expects many more in the coming months.

focus, their resources in litigating these actions. This Panel has noted:

> Since a Section 1407 transfer is for pretrial proceedings only, there is usually no need for the parties and witnesses to travel to the transferee district for depositions or otherwise. Furthermore, the judicious use of liaison counsel, lead counsel and steering committees will eliminate the need for most counsel ever to travel to the transferee district. And it is most logical to assume that prudent counsel will combine their forces and apportion the workload in order to streamline the efforts of the parties and witnesses, their counsel and the judiciary, thereby effectuating an overall savings of cost and a minimum of inconvenience to all concerned.

In re Baldwin-United Corp. Litig., 581 F. Supp. 739, 740-41 (J.P.M.L. 1984) (citations omitted). Thus, by allowing the centralization and coordination of pretrial proceedings for these related actions, and the anticipated flood of actions in the future, current and future plaintiffs will have a single, organized, and easily accessible forum to have the bulwark of overlapping discovery adjudicated. Centralization and pretrial coordination will "eliminate duplicative discovery, prevent inconsistent pretrial rulings . . . and conserve the resources of the parties, their counsel and the judiciary." *In re Temporomandibular Joint (TMJ) Implants*, 844 F. Supp. at 1554.

II. Centralization and Pretrial Coordination in the Central District of California Is Appropriate.

The selection of an appropriate transferee court is based on a balancing test of several factors, no one of which is dispositive. *See* Manual For Complex Litigation (Fourth) § 20.131 (2004) (citing Robert A. Cahn, *A Look at the Judicial Panel on Multidistrict Litigation*, 72 F.R.D. 211, 214-15 (1977)). These factors include "where the largest number of cases is pending, where discovery has occurred, where cases have progressed furthest, the site of the occurrence of the common facts, where the cost and inconvenience will be minimized, and the experience, skill, and caseloads of available judges." *Id.* Movants submit that coordination in the Central District of California is the most logical and convenient forum.

A. The Central District Has the First-Filed, Most Procedurally Advanced, and Largest Number of Cymbalta Withdrawal Actions.

The Central District of California has the oldest, most developed, and largest number of Cymbalta Withdrawal cases. There are currently seven (7) cases pending before judges in the Central District of California, the oldest of which was filed in 2012.[6] The *Saavedra* class action, which was the first Cymbalta Withdrawal case, is pending before Judge Wilson. *See In re Chrysler LLC 2.7 Liter V-6 Engine Oil Sludge Products Liab. Litig.*, 598 F. Supp. 2d 1372, 1373 (J.P.M.L. 2009) (centralizing litigation in the District of New Jersey because pending action was "pending longer than the other actions."). In *Saavedra*, the parties have engaged in substantial litigation, including a motion to dismiss, a motion for summary judgment, a motion to compel, expert discovery on the issue of damages, and two pending (fully briefed) motions for class certification. *See, e.g.*, *In re Enfamil Lipil Mktg. & Sales Practices Litig.*, 764 F. Supp. 2d 1356, 1357 (J.P.M.L. 2011) (centralizing litigation before district court that had engaged in significant litigation related to class certification). Judge Wilson has issued orders that address several important issues in this litigation, such as the learned intermediary doctrine and federal preemption. *See Saavedra v. Eli Lily & Co.*, 2:12-CV-9366-SVW-MAN, 2013 WL 6345442 (C.D. Cal. Feb. 26, 2013); *Saavedra v. Eli Lilly & Co.*, 2:12-CV-9366-SVW-MAN, 2013 WL 3148923 (C.D. Cal. June 13, 2013). Similarly, Judge King has three cases before him—*Carter*, *Herrera*, and *Hexum*—which is more than any other court. And, while Judge King has not yet issued any substantive orders in those cases, the parties are engaged in discovery that currently has a December 2014 deadline. Thus, "[t]he Central District of California is an appropriate transferee forum because the first-filed and most procedurally advanced actions are pending there." *In re Land Rover LR3 Tire Wear Products Liab. Litig.*, 598 F. Supp. 2d 1384, (Feb. 23, 2009).

B. The Central District of California Has the Infrastructure, Available Judges, and

[6] There are, in total, ten (10) pending cases filed in federal courts in California.

Institutional Knowledge to Efficiently Manage this MDL.

The Central District of California is uniquely qualified to handle and manage this MDL. In 2013, the Central District of California had the second highest number of civil court filings and the highest number of civil court terminations.[7] The median time from filing to disposition for all civil cases was only 5.9 months.[8] *See In re Classicstar Mare Lease Litig.*, 528 F. Supp. 2d 1345, 1347 (J.P.M.L. 2007) ("[T]he district's general docket conditions permit us to make the Section 1407 assignment knowing that the court has the resources available to manage this litigation."). In addition, there are more active MDLs in the Central District of California than in any other district, but no active MDLs before Judges Wilson or King.[9] Thus, the Central District has both the infrastructure to support the coordination of these related Cymbalta withdrawal actions and two potential judges with familiarity and availability. Moreover, *In re Paxil* (MDL No. 1574), an MDL involving nearly identical personal injuries related to withdrawal from an antidepressant, was successfully centralized and coordinated in the Central District of California before the Honorable Mariana R. Pfaelzer. Thus, the Central District of California has institutional familiarity and knowledge about how to manage this type of litigation.

C. The Central District of California Is an Accessible and Convenient Forum for an MDL that Has No Natural Geographic Nucleus.

The Central District of California is an accessible and convenient forum for all parties and witnesses. Plaintiffs in the currently pending actions—and in future cases that will be filed—are geographically dispersed across the country, making no single district *most* convenient to all plaintiffs. But the most cases currently on file—indeed, the most advanced cases—currently

[7] *See* Administrative Office of the United States Courts, *2013 Annual Report of the Director: Judicial Business of the United States Courts*, Statistical Tables C-3 and C-4A (2014), *available at* http://www.uscourts.gov/Statistics/JudicialBusiness/2013/statistical-tables-us-district-courts-civil.aspx
[8] *Id.* at Table C-5.
[9] United States Judicial Panel on Multidistrict Litigation, *MDL Statistics Report-Distribution of Pending MDL Dockets by District* (July 15, 2014), *available at* http://www.jpml.uscourts.gov/sites/jpml/files/Pending_MDL_Dockets_By_District-July-15-2014.pdf

reside in the Central District of California. And, as demonstrated by Lilly's participation in the ongoing Cymbalta Withdrawal cases in the Central District of California for the past two years, Los Angeles and the Central District of California have proven to be a convenient and workable forum for Lilly and its attorneys. Similarly, although Plaintiffs' counsel are likely to come from various parts of the country, undersigned counsel expects to represent many plaintiffs in this litigation and is based in Los Angeles. [10]

Practically, the Central District of California, in Los Angeles, is one of the most convenient venues in the country. Los Angeles has three major airports (Los Angeles International Airport (LAX) LA/Ontario International Airport, and John Wayne Airport) and three smaller airports (Bob Hope Airport, Palm Springs International Airport, and Long Beach Airport). LAX is a hub for United Airlines and American Airlines and handles more "origin and destination" (*i.e.*, not connecting) passengers than any other airport in the world. Los Angeles is certainly one of the easiest cities to travel to, from anywhere in the United States. Coordination of proceedings in a major metropolitan venue such as the Central District of California allows for superior access and convenience.

D. Centralization and Coordination Before Judge Wilson in the Central District of California Is the Logical Choice and Would Avoid Complications Associated with the *Saavedra* Class Action.

The *Saavedra* putative class action is a mature litigation. The parties have fully briefed class certification and have conducted expert discovery on the issue of damages. In total, the parties have filed ten separate briefs related to class certification and have participated in two lengthy oral arguments. Judge Wilson took the matter under submission five months ago and it is ripe for disposition. Due to Judge Wilson's familiarity with the litigation and the advanced

[10] Baum, Hedlund, Aristei & Goldman, P.C. ("Baum Hedlund"), one of the law firms representing the Movants here, was lead counsel for the MDL plaintiffs in a similar MDL proceeding, *In re Paxil* in the Central District of California, and is headquartered in Los Angeles.

posture of the *Saavedra* class action, centralization before Judge Wilson is the logical choice. Indeed, Judge Wilson is not a stranger to MDL proceedings. *See, e.g.*, *In re Live Concert Antitrust Litig.*, 429 F. Supp. 2d 1363, 1364 (J.P.M.L. 2006) (centralizing MDL before Judge Wilson). And, should Judge Wilson certify a class in *Saavedra*, centralization before him would allow coordination between class claimants and personal injury suits. *See In re Enfamil.*, 764 F. Supp. 2d at 1357 (district court overseeing class actions in unique position to administer parallel personal injury claims); *In re Qwest Commc'ns Int'l, Inc., Sec. & "Erisa" Litig. (No. II)*, 444 F. Supp. 2d 1343, 1345 (J.P.M.L. 2006) (centralizing cases before district court because the court was also presiding over similar class action).

Of course, should the Panel select a different judge to oversee this MDL, the *Saavedra* class action would need to remain with Judge Wilson. It would be unrealistic and impractical to re-brief and re-litigate the class certification issues and attempt to get another judge up-to-speed, especially in light of the time Judge Wilson has already committed to the case. This is why *Saavedra* is not listed on the Schedule of Actions—although the advanced posture of *Saavedra* makes Judge Wilson the ideal transferee court to oversee this MDL, it also makes *Saavedra* ill suited for consolidation before an MDL that is not before Judge Wilson.

E. Alternatively, Centralization and Coordination before Judge King in the Central District of California Would Be Viable Option.

Judge King presides over three Cymbalta Withdrawal personal injury cases—*Carter*, *Herrera*, and *Hexum*. These lawsuits were filed in 2013 and are scheduled to complete discovery in December 2014. As it stands, Judge King presides over more cases than any other judge and is fatherest along discovery-wise. Although Judge King has not issued any substantive rulings in *Carter*, *Herrera*, or *Hexum*, he has the requisite familiarity with these cases such that he would be an excellent candidate to oversee an MDL proceeding. And, since Judge King is in

the same district as Judge Wilson, they would be able to coordinate the *Saavedra* class action with the Cymbalta Withdrawal personal injury MDL to ensure orderly pretrial litigation. Thus, should the Panel decide to select someone other than Judge Wilson to oversee the Cymbalta Withdrawal MDL, Judge King would be an excellent candidate.

CONCLUSION

Based on the foregoing, Movants respectfully request that the Panel order coordinated pretrial proceedings for Cymbalta withdrawal injury cases and transfer all such pending and future cases to the Central District of California, with either the Honorable Stephen V. Wilson or the Honorable George H. King presiding.

DATED: August 15, 2014
Los Angeles, California

Respectfully submitted,

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Exhibit C

BEFORE THE UNITED STATES
JUDICIAL PANEL ON MULTIDISTRICT LITIGATION

MDL No. 2576

In re: Cymbalta Products Liability Litigation

Oral Argument Requested

RESPONSE TO PLAINTIFFS' MOTION PURSUANT TO 28 U.S.C. § 1407 TO TRANSFER RELATED ACTIONS FOR COORDINATED PRETRIAL PROCEEDINGS

The Plaintiffs' proposal to create an MDL to address "discontinuation" adverse events arising from Eli Lilly and Company's medicine Cymbalta® (duloxetine) implicates many of the concerns the Panel has expressed when contemplating the unintentional consequences of creating a centralized proceeding that would neither result in "convenience" for the parties and witnesses nor "promote the just and efficient conduct" of the lawsuits.

First, centralization here would violate this Panel's bedrock guidance that centralization is not appropriate where individual fact issues predominate over common factual questions. There are no disputed "common" questions that would justify an MDL: here there is no dispute about the risk that Cymbalta, like every other antidepressant in its class, can lead to certain side effects upon the discontinuation of the medicine — a risk that was well known at the launch of the medicine a decade ago and specified clearly in the labeling from the beginning.

Rather than presenting a set of core common questions, to date, this litigation has been dominated by individual issues, as best evidenced by the handful of individual lawsuits that the same firm which seeks centralization here ("Movant's Counsel") has prosecuted over the last 18 months. Because of the well-recognized risk of discontinuation side effects with antidepressants, Plaintiffs, to proceed on their claims, face the formidable task of demonstrating that their physicians were unaware of this risk. For this reason, two district courts handling these actions had sensibly put in place a scheduling order to bring this central issue to the fore by

requiring the early deposition of the prescribing physician and prompt dispositive briefing thereafter. In the first, the plaintiff's physician confirmed that he was well aware of Cymbalta's potential to cause such side effects when discontinuing the medicine, and the Court therefore granted summary judgment for Lilly. *See Carnes v. Eli Lilly and Co.*, 2013 WL 6622915 (D.S.C. Dec. 16, 2013). In the second, the plaintiff's medical provider offered similar testimony about her knowledge, and Lilly's summary judgment motion is pending. *See McDowell*, No. 13-cv-03786, ECF No. 17 (S.D.N.Y.). Allowing a mechanism whereby a large number of cases can be filed and shielded from the prompt deposition of the relevant prescribing physicians would only serve to prolong, not expedite, the resolution of the litigation. *See In re American-Manufactured Drywall Prods. Liab. Litig.*, 716 F. Supp. 1367, 1368 (J.P.M.L. 2010) ("The proponents of centralization have not convinced us that any efficiencies from centralization would outweigh the multiple individualized issues, including ones of liability and causation, that these actions appear to present.").

Second, this litigation does not present the unique coordination challenges for which MDL centralization is reserved. The proposed MDL is comprised of a small number of actions, the vast majority of which were filed in the days immediately prior to Plaintiffs' centralization motion (presumably to ward off the Panel's prior admonitions refusing to centralize small numbers of actions). For the past eighteen months, Movants' Counsel and national counsel for Lilly have cooperatively and successfully coordinated discovery and dispositive motions practice across the initial individual cases filed across five federal judicial districts. Indeed, in the individual lawsuits that the Plaintiffs' lead firm has prosecuted, Lilly has produced over 1.8 million pages of documents reflecting the key science, testing, and labeling documents for Cymbalta, a production that Lilly has voluntarily made applicable to all of the

pending individual cases. Plaintiffs' counsel has also taken three Rule 30(b)(6) depositions of Lilly witnesses concerning Cymbalta. By agreement, those depositions were noticed for all of the pending cases. Given the nearly complete overlap in counsel across the newly-filed cases and virtually identical discovery sought against Lilly, there is no reason that the parties may not proceed with the voluntary cooperation that this Panel has cited as a desirable alternative to MDL centralization.

In short, there is little to be gained from MDL centralization but delaying the ultimate resolution of these cases and the warehousing of cases that on their own merits would not warrant prosecution. The MDL procedures should not be utilized to create a "Field of Dreams" that attracts a swath of meritless claims that can be shielded from individualized discovery under the Federal Rules.

While Lilly submits that the Panel should therefore decline to centralize these cases under Section 1407, if the panel does decide to centralize these actions, Lilly respectfully submits that the actions should be centralized in a court in the Eastern United States more convenient to Lilly and its employee witnesses, its defense counsel in Washington DC, and Movant's Counsel in Philadelphia.

I. BACKGROUND

A. Overview of Cymbalta and Discontinuation Warnings

Cymbalta is an FDA-approved prescription medicine manufactured by Lilly to treat severe depression, anxiety, and pain disorders. Plaintiffs in the subject actions have alleged that Lilly failed to warn adequately of possible side effects related to discontinuing Cymbalta treatment. These effects are referred to as "discontinuation-emergent adverse events."

In litigating failure-to-warn products liability cases, the "learned intermediary doctrine" applies in the vast majority of jurisdictions, meaning that the core issue is whether a

plaintiff's prescribing physician, as the "learned intermediary" between the pharmaceutical manufacturer and the patient, possessed independent knowledge of the risk at issue or would have changed his or her prescribing decision had the medicine's warning materials been different. Where a prescribing physician would not have changed his or her decision to prescribe a medicine had the warning been different, or where a prescribing physician has independent knowledge of the symptoms alleged, there is no proximate causation between the allegedly inadequate warning and the plaintiff's injuries, so the claims fail.

In this case, from the moment that FDA first approved Cymbalta in 2004, Cymbalta's FDA-approved label has included a detailed, three-paragraph warning on the risk of discontinuation symptoms that has remained largely unchanged in the ensuing decade. The label by 2008 read as follows:

> 5 WARNINGS AND PRECAUTIONS
>
> . . . .
>
> 5.6 Discontinuation of Treatment with Cymbalta
>
> Discontinuation symptoms have been systematically evaluated in patients taking duloxetine. Following abrupt or tapered discontinuation in placebo-controlled clinical trials, the following symptoms occurred at a rate greater than or equal to 1% and at a significantly higher rate in duloxetine-treated patients compared to those discontinuing from placebo: dizziness, nausea, headache, fatigue, paresthesia, vomiting, irritability, nightmares, insomnia, diarrhea, anxiety, hyperhidrosis and vertigo.
>
> During marketing of other SSRIs and SNRIs (serotonin and norepinephrine reuptake inhibitors), there have been spontaneous reports of adverse events occurring upon discontinuation of these drugs, particularly when abrupt, including the following: dysphoric mood, irritability, agitation, dizziness, sensory disturbances (e.g., paresthesias such as electric shock sensations), anxiety, confusion, headache, lethargy, emotional lability, insomnia, hypomania, tinnitus, and seizures. Although these events are generally self-limiting, some have been reported to be severe.

> Patients should be monitored for these symptoms when discontinuing treatment with Cymbalta. A gradual reduction in the dose rather than abrupt cessation is recommended whenever possible. If intolerable symptoms occur following a decrease in the dose or upon discontinuation of treatment, then resuming the previously prescribed dose may be considered. Subsequently, the physician may continue decreasing the dose but at a more gradual rate [see Dosage and Administration (2.4)].

Cymbalta Physician Packet Insert (June 2008). This warning lists more than a dozen symptoms that occurred following discontinuation in clinical trials "at a rate greater than or equal to 1% and at a significantly higher rate in [Cymbalta]-treated patients compared to those discontinuing from placebo." The label also warns of the possibility of "severe" side effects upon the discontinuation of Cymbalta, and it explicitly instructs physicians to taper patients off Cymbalta and to closely monitor patients for those symptoms when discontinuing the medicine.[1]

Even apart from the warning on Cymbalta's label, the risk of such symptoms is commonly understood in the medical community. The American Psychiatry Association's Practice Guidelines for the Treatment of Patients With Major Depressive Disorder, for instance, cautions that "abrupt discontinuation of SNRIs [Serotonin-Norepinephrine Reuptake Inhibitors] should be avoided wherever possible," because discontinuation symptoms may occur. *See* http://psychiatryonline.org/data/Books/prac/PG_Depression3rdEd.pdf (last visited September 8, 2014), at 20, 40. Indeed, such information is widely available on virtually all medical information web resources. *See, e.g.*, WebMD, Antidepressant Withdrawal, *available at* http://www.webmd.com/depression/guide/withdrawal-from-antidepressants ("Antidepressant withdrawal, more correctly called antidepressant discontinuation syndrome, refers to a unique set

[1] All of the relevant versions of Cymbalta's label contain this three-paragraph warning and are available on FDA's website: http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Overview&DrugName=CYMBALTA (last visited September 8, 2014). *See also* Plaintiffs' Motion at 4-5.

of symptoms that can develop after you stop taking an antidepressant.") (last visited September 8, 2014); Mayo Clinic (Daniel K. Hall-Flavin, M.D.), Antidepressant Withdrawal FAQ, *available at* http://www.mayoclinic.org/diseases-conditions/depression/expert-answers/antidepressant-withdrawal/faq-20058133 ("Antidepressant withdrawal is possible if you abruptly stop taking an antidepressant, particularly if you've been taking it longer than six weeks. Symptoms of antidepressant withdrawal are sometimes called antidepressant discontinuation syndrome") (last visited September 8, 2014).[2]

Notwithstanding this extensive public and medical knowledge of these well-characterized risks with such medicines, the core allegation in Plaintiffs' complaints is that Lilly's warning to physicians is somehow misleading because it provides a list of the specific discontinuation symptoms that were observed in clinical trials "at a rate greater than or equal to 1%." To be clear, a higher threshold inclusion number would have meant that *fewer* symptoms were warned of on the label. In clinical trials, some of the individual listed symptoms occurred at rates of between 1% and 2%, or between 2% and 5%, and above, so Lilly's Cymbalta warning would have been less informative had Lilly used a higher inclusion threshold. In an argument yet to be ratified by a single prescribing medical professional in the existing actions, Plaintiffs contend that their physicians must have been misled by Lilly's warning into thinking that *only*

[2] Even this Panel confronted this issue over a decade ago, when it created MDL No. 1574 relating to such discontinuation side effects for the antidepressant Paxil® (paroxetine). *See* 296 F. Supp. 2d 1374 (J.P.M.L. 2003). Of special note is the fact that the Paxil labeling principally at issue in MDL No. 1574, which this panel created in 2003, was a version that ***pre-dated*** FDA's decision to impose "class labeling" for discontinuation side effects for all similar antidepressants. In other words, the discontinuation warning that Cymbalta had from the moment it launched in 2004 included the extensive warning language that FDA adopted for the entire class ***after*** the events that precipitated the Paxil discontinuation litigation in the first place.

1% of patients who abruptly discontinue Cymbalta (which itself is contrary to the label's instruction to taper any discontinuation) would suffer these types of side effects.

B. First Group of Cymbalta Discontinuation Cases (2012-2013)

The first Cymbalta action alleging discontinuation side effects against Lilly was a putative class action filed in October 2012. (The motion for class certification in that case, *Saavedra v. Eli Lilly and Company*, No. 12-cv-9366 (C.D. Cal.), is currently pending.) That was followed by five individual-plaintiff actions filed between March and June 2013. That set of cases included actions filed in the District of South Carolina (*Carnes*, dismissed December 16, 2013, upon Lilly's motion for summary judgment), the Central District of California (*Carter*, *Herrera*, and *Hexum*), the District of Arizona (*Seagroves*), the Southern District of New York (*McDowell*), and a case filed in the Eastern District of Pennsylvania (*Lister*) that Plaintiffs later voluntarily dismissed. Lilly has been the sole defendant in each of these cases.

The complaints contain nearly identical factual allegations and claims, alleging at bottom that Lilly did not adequately warn of the potential risks upon discontinuing Cymbalta treatment. The legal theories are also virtually identical across all the filed actions, with slight variations based on state law and depending on whether the patient's spouse is a named plaintiff.

Discovery has proceeded in each of these cases, and some have already reached the dispositive motion stage. The *Carnes* court granted summary judgment to Lilly, finding that the plaintiff had not proven proximate causation. Another motion for summary judgment is under submission in *McDowell*, with argument scheduled for September 17, 2014.

C. The Pre-Petition Wave of Cases (August 2014)

In August 2014, the same counsel who had filed the first set of Cymbalta cases filed a burst of new actions against Lilly between August 8 and August 13 — a total of 21 new

cases.[3] The Plaintiffs chose to file these new suits, all of which are virtually identical in content and make the same allegations as the first set of lawsuits filed last year, in the following jurisdictions: four were filed in the Central District of California (*Barrett*, *Caporale*, *Hollowell*, *O'Shea*), two in the Eastern District of California (*Cheshier*, *Woodruff*), two in the Eastern District of North Carolina (*Whitworth*, *Williams*), one in the Southern District of California (*Wheeler*), and one each in the District of Colorado (*Cheney*), Middle District of Florida (*Bhoge*), Southern District of Florida (*Gollin*), Northern District of Georgia (*Couch*), Western District of Louisiana (*Fairbanks*), District of Maryland (*Boling*), District of Minnesota (*McCabe*), Northern District of Ohio (*Mayes*), District of Oregon (*Loux*), Western District of Pennsylvania (*Rossero*), Eastern District of Washington (*Wagner*), and Western District of Wisconsin (*Streeter*). Without bothering to serve any of these lawsuits on Lilly (indeed, to this date Lilly has still not been served in any of these new lawsuits), Movant's Counsel immediately filed their centralization motion, which Lilly learned about not through service — the motion had simply been dropped in the mail — but from a media outlet that had been provided the Motion the day it was filed.

Three additional actions have since been filed and noticed as related to this proceeding (*Kelly* — filed August 26, 2014 in the Northern District of California, and *Schaffer* and *Scherer* — filed August 27, 2014 in the Eastern District of Missouri). All of these actions largely follow the first group of cases in the substance of their factual allegations and legal argument.

[3] Although the reason for this transition is not clear, it appears that Movant's Counsel — the same firm that has prosecuted a handful of individual similar cases over the last eighteen months — has decided to shift legal strategy away from the burdens of litigating the individual lawsuits of questionable merit they have brought to date.

II. ARGUMENT

The Plaintiffs' centralization motion should be denied. While Plaintiffs have apparently attempted to lodge a sufficient number of cases to overcome the Panel's prior skepticism when too few cases are sought to be centralized, the number nevertheless remains more than manageable and hardly reflects a volume where centralization is the only option. Indeed, Lilly is committed to devoting the resources to promptly work up each of the cases in the respective districts, and at the same time work cooperatively to provide appropriate discovery from Lilly to be utilized across all the cases.

It is the case-specific issues, however, that will dominate this litigation: each individual plaintiff's use of Cymbalta, and each physician's decision to prescribe it. These individual factual questions predominate over common questions, and any common discovery can be conducted (and already has been conducted) through voluntary cooperation rather than a centralized MDL. Lilly therefore opposes centralization because it will not enhance convenience of the parties or counsel (just the opposite) and it will delay, not advance, the resolution of the individual actions.

In the alternative, Lilly submits that the Central District of California — 2,000 miles from Lilly's headquarters and nearly 3,000 miles from Lilly's counsel in Washington and Plaintiffs' counsel in Philadelphia — is decidedly inconvenient. Lilly therefore recommends that any proceeding be centralized in the Eastern United States in one of the districts set forth below.

A. The Panel Should Not Centralize These Actions.

1. Centralization is inappropriate where complicated individual questions of fact predominate over common questions, and where discovery will necessarily focus on individualized actions.

Where individual factual questions predominate over the common factual issues alleged by Plaintiffs, MDL centralization is not warranted. *See, e.g., In re Electrolux Dryer*

Prods. Liab. Litig., 978 F. Supp. 2d 1376, 1377 (J.P.M.L. 2013) ("On the present record, it appears that individualized facts . . . will predominate over the common factual issues alleged by plaintiffs."); *In re Ocala Funding, LLC, Commercial Litig.*, 867 F. Supp. 2d 1332 (J.P.M.L. 2012) ("Individualized issues concerning each party's rights and duties under separate sets of contracts, and with different contracting parties, appear to predominate among the actions."); *In re American-Manufactured Drywall Prods. Liab. Litig.*, 716 F. Supp. 2d 1367, 1368 (J.P.M.L. 2010) ("The proponents of centralization have not convinced us that any efficiencies from centralization would outweigh the multiple individualized issues, including ones of liability and causation, that these actions appear to present.").

In this case, Lilly does not dispute that the subject actions share some common issues. All of the plaintiffs allege that they were prescribed Cymbalta, that they discontinued taking Cymbalta, and that upon discontinuation they suffered symptoms that Lilly warned of on Cymbalta's label. But the common issues, such as the fact that Lilly studied and warned of the risks of discontinuation with Cymbalta, are not in material dispute and require little discovery that has not already been conducted in the pending Cymbalta cases that are the farthest along in the discovery process.

It is the individual issues, by contrast, and the facts particular to each case that drive this litigation. As the District Court for the District of South Carolina wrote in granting Lilly's motion for summary judgment as to one of the Cymbalta plaintiffs, each plaintiff must establish that Lilly's purportedly inadequate warning was the "proximate cause of the plaintiff's injury," and that a different warning "would have changed the treating physician's decision to prescribe the product for the plaintiff." *Carnes*, 2013 WL 6622915, *3 (D.S.C. Dec. 16, 2013) (internal quotation marks and citations omitted). *See also, e.g., Alston v. Caraco*

Pharmaceutical, Inc., 670 F. Supp. 2d 279 (S.D.N.Y. 2009) (plaintiff must show that "a failure to warn . . . was the proximate cause of his injuries"). These individualized issues of proximate causation require extensive inquiry into the actions and knowledge of each plaintiff's prescribing physician(s) and the individual plaintiffs themselves. Among other questions, a court must inquire as to which patient-specific factors the treating physician considered in deciding to prescribe Cymbalta, whether the physician read the discontinuation warning on Cymbalta's label or otherwise had independent knowledge of the risk of such symptoms when stopping a medicine like Cymbalta, whether the physician somehow did not understand the discontinuation warning, and whether the warning influenced the physician's decision to prescribe. Given the central importance of these individualized and fact-driven questions, the individual issues predominate over the common questions of fact alleged in the subject litigations.

Plaintiffs hope to present the opposite impression, suggesting that common issues of fact will drive this litigation. For instance, Plaintiffs write that one of the common questions is "Cymbalta's capacity to cause withdrawal injuries." *See* Plaintiffs' Motion at 1. But Cymbalta's *capacity* to cause discontinuation symptoms is not a disputed issue. Indeed, Cymbalta's labeling explicitly warns that Cymbalta (like every similar antidepressant) can cause such discontinuation symptoms, and recommends a tapering of the medicine to reduce the chance of these symptoms occurring. This litigation, unlike many pharmaceutical products liability cases the panel has previously confronted, thus does not present questions of *general causation* that are uniquely suitable for decision by an MDL judge. Instead, Lilly's alleged liability hinges primarily on individualized, fact-specific determinations of proximate causation, and whether the purportedly inadequate warning caused the injuries complained of by each specific plaintiff. It is the individual transferor courts and not an MDL court, therefore, that will

have to confront those key issues, so there is little efficiency to be gained from transfer to an MDL. *See In re Lipitor Mktg., Sales Practices & Prods. Liab. Litig.*, 959 F. Supp. 2d 1375, 1376 (J.P.M.L. 2013) ("As always in this type of litigation, a highly individualized inquiry is necessary to determine whether any particular plaintiff developed type 2 diabetes as a result of taking Lipitor."); *In re Abbott Labs., Inc. Similac Prods. Liab. Litig.*, 763 F. Supp. 2d 1376 (J.P.M.L. 2011) (concluding that "individual facts contained in these actions will predominate over any alleged common fact questions").

2. Centralization is not necessary because informal cooperation between national counsel for the defendant and national counsel for Plaintiffs will realize the same efficiencies as an MDL.

Any coordination that *would* aid efficient resolution of the subject actions can be achieved without transfer to an MDL. As this Panel has indicated, voluntary cooperation is a preferable "[a]lternative[] to transfer . . . that may minimize whatever possibilities could arise of duplicative discovery." *In re Table Saw Prods. Liab. Litig.*, 641 F. Supp. 2d 1384 (J.P.M.L. 2009). *See also In re Mirena IUS Levonorgestrel-Related Prods. Liab. Litig.*, MDL No. 2559, 2014 WL 4049821 (J.P.M.L. Aug. 12, 2014) ("[I]nformal cooperation among the involved attorneys is both practicable and preferable to centralization."). Voluntary cooperation is especially practicable where the actions "are filed by a single plaintiffs' counsel, and name the same defendant, which has national counsel coordinating its response to [the] litigation." *Mirena*, 2014 WL 4049821 at *1. *See also In re Rite Aid Corp. Wage & Hour Empl. Practices Litig.*, 655 F. Supp. 2d 1376, 1377 (J.P.M.L. 2009) (voluntary coordination is "particularly appropriate" where many or all plaintiffs share counsel); *American-Manufactured Drywall*, 716 F. Supp. 2d at 1368 (shared counsel "facilitate cooperation among the parties and coordination of the actions").

Here, the plaintiffs in nearly all of the proposed MDL actions are represented by the same counsel. *See* Schedule of Actions, ECF No. 1-2 at 5-6. The same counsel, led by the Pennsylvania firm of Pogust Braslow & Millrood LLC, have represented plaintiffs in discontinuation-related litigation against Lilly concerning Cymbalta in the six cases filed prior to August 2014. *See In re Boehringer Ingelheim Pharm., Inc. Fair Labor Standards Litig.*, 763 F. Supp. 2d 1377, 1378 (J.P.M.L. 2011) ("[T]he presence of common counsel for moving plaintiffs in actions filed shortly before the motion for centralization might also weigh against centralization.").[4] And in the nearly 18 months since the first discontinuation-related litigation concerning Cymbalta was filed, Lilly's undersigned counsel and plaintiffs' counsel have worked cooperatively throughout all stages of discovery. Plaintiffs have offered no reason why that cooperation cannot be expected to continue in the other, recently-filed actions.

Moreover, the common issues in the subject actions are likely to require the same discovery from Lilly. Lilly has already produced 1.8 million pages of documents responsive to the plaintiffs' requests in three of the subject actions, including materials from the Investigational New Drug Application and New Drug Application files for Cymbalta, in response to 167 Requests for Production propounded by the plaintiffs. Lilly has also presented company representatives for deposition pursuant to Rule 30(b)(6) in the areas of drug safety for Cymbalta, Cymbalta's labeling, and sales training for Cymbalta. Because the newly-filed subject actions contain no substantively new allegations or novel theories, it is unlikely that much if any additional discovery will be required from Lilly. And as to the documents already produced,

[4] A notice of related actions has been filed by different counsel in three additional cases. It is not clear from the face of the complaints whether these additional counsel are coordinating with Pogust Braslow, but the text of the complaints are virtually identical and the coordinated timing of their recent spate of filings suggests closely-affiliated coordination.

Lilly of course will not oppose use of those documents in any of the additional discontinuation-related cases in the same manner these are available in the pending cases.

Even setting aside this substantial overlap in discovery and the existing voluntary cooperation between counsel, which weighs against creation of an MDL, the sheer number of cases filed by Movants' Counsel does not justify consolidation. First, centralization should be denied where the same law firm attempts to manufacture an MDL by filing a series of duplicative lawsuits in different jurisdictions. *See In re CVS Caremark Corp. Wage and Hour Employment Practices Litig.*, 684 F. Supp. 2d 1377, 1379 (J.P.M.L. 2010) (denying certification where the movants were "all represented by the same law firm," which began to litigate one action more than a year earlier, then filed others "immediately prior to filing this Section 1407 motion."). Second, and more fundamentally, Movants' Counsel have been prosecuting Cymbalta discontinuation litigation against Lilly for nearly two years, in the form of a half-dozen individual lawsuits and a putative class action that has not been certified. Plaintiffs' claims of "hundreds" of additional actions in the offing — Plaintiffs leave unsaid why those actions have yet to materialize — warrants a skeptical eye. *See In re Lipitor*, 959 F. Supp. 2d at 1376 (the Panel is "disinclined to take into account the mere possibility of future filings in our centralization calculus"); *see also In re CVS Caremark*, 684 F. Supp. 2d at 1379 ("[W]here a Section 1407 motion appears intended to further the interests of particular counsel more than those of the statute, we would certainly find less favor with it.").

B. If the Panel Determines That An MDL Is Warranted, The Actions Should Not Be Sent To The Central District Of California

For the reasons set forth above, the Panel should deny Plaintiffs' motion for transfer. If the panel nevertheless determines that the actions should be centralized, it should not transfer the actions to the Central District of California.[5]

The Panel considers the following key factors in selecting an appropriate transferee district: accessibility of the transferee district for parties, witnesses, and counsel; the respective MDL and overall caseload statistics for the proposed transferee district courts; and the location of the parties, witnesses, and documents. *See, e.g., In re Mirena IUD Products Liab. Litig.*, 938 F. Supp. 2d 1355, 1358 (J.P.M.L. 2013); *In re Camp Lejeune, North Carolina Water Contamination Litigation*, 763 F. Supp. 2d 1381, 1382 (J.P.M.L. 2011); *In re Trasylol Prods. Liab. Litig.*, 545 F. Supp. 2d 1357, 1358 (J.P.M.L. 2008). As explained at greater length below, application of these factors weighs in favor of transfer to a district on the East Coast with a judge experienced in a pharmaceutical products liability MDL. Lilly proposes the Middle District of Florida, Northern District of Ohio, and the Northern District of Georgia as appropriate districts.

1. A court in the Eastern United States would be the most accessible and cost-effective for parties, witnesses, and counsel.

Lilly is headquartered in Indianapolis, Indiana. Lilly's national counsel for discontinuation-related Cymbalta litigation is Covington & Burling LLP, in Washington, D.C. And lead national counsel for individual Plaintiffs has been the firm of Pogust Braslow &

[5] Because the *McDowell* case has been fully briefed on summary judgment, with argument to occur on September 17, 2014, it should not be included in any transfer. *See In re L.E. Lay & Co. Antitrust Litig.*, 391 F. Supp. 1054, 1056 (J.P.M.L. 1975) (noting the Panel's reluctance "to transfer any action that has an important motion under submission with a court"); *In re Res. Exploration, Inc. Sec. Litig.*, 483 F. Supp. 817, 822 (J.P.M.L. 1980) (deferring decision on transfer "because of the pendency of the defendants' motion for summary judgment, which is fully submitted to the potential transferor judge").

Millrood, LLC, of Conshohocken, Pennsylvania, outside of Philadelphia. The Los Angeles, California firm of Baum Hedlund, Aristei & Goldman, P.C. additionally appears to have joined Plaintiffs' efforts, appearing as counsel in many of the newly-filed individual actions.[6]

Because Lilly is the only defendant in the subject actions, and because the majority of the counsel involved are located on the East Coast, the parties will be best served by transfer to a court in the Eastern United States. If these actions are centralized in California, there will be considerable inconvenience and inefficiency for Lilly and its counsel. Presumably, any MDL judge will hold regular case management conferences for the respective lead counsel, in addition to hearings on motions, discovery matters, and related proceedings. Traveling nearly 3,000 miles to California for such proceedings is not only expensive, but because of the travel time from the East Coast typically requires 2-3 days of lawyer time. Without diminishing the Plaintiffs' claimed injuries, they are for the most part alleged to be transient in nature and without physical impairment or disability.[7] The corresponding value of such cases could quickly be outstripped merely by the costs of repeated cross-country travel. Such a result would be neither just nor efficient.

Finally, while the plaintiff-specific witnesses will be all over the country, the Lilly-related witnesses and documents will be located in the Eastern United States. Indeed, in the pending Cymbalta cases in the Central District of California, *Carter*, *Herrera*, and *Hexum*, plaintiffs' counsel have taken three 30(b)(6) depositions of Lilly witnesses in Indianapolis.

[6] Although counsel of record in the *Saavedra* class action, Baum Hedlund has had no role in any of the pending individual suits until immediately prior to the filing of Plaintiffs' centralization motion. Pogust Braslow has had primary responsibility for the prosecution of those cases.

[7] The plaintiff in *McDowell*, for instance, testified that he suffers no continuing symptoms today and that most of his symptoms stopped within weeks and/or months of discontinuing Cymbalta. *See McDowell v. Eli Lilly and Co.*, No. 13-cv-03786, ECF. No. 19 at 8 (July 7, 2014).

(Those depositions were also cross-noticed by agreement for the other two then-pending cases, *Seagroves* (D. Ariz.) and *McDowell* (S.D.N.Y.).)

2. Apart from Plaintiffs' attorneys' choice to file cases there, California has no particular connection to this litigation.

As set forth above, California has no particular connection to the Cymbalta discontinuation suits that have been filed. Lilly is not located in California, nor is its counsel. And the firm that has thus far conducted this litigation for Plaintiffs, the Pogust Braslow firm, is also located on the East Coast. While it is true that the plurality of subject actions are pending in California, most of those cases were filed in the span of a few days immediately prior to Plaintiffs' transfer motion. And in any case, the fact that Plaintiffs have chosen to file a comparatively larger number of cases in California than in other jurisdictions has no bearing on where to transfer an MDL that purports to be national in scope. *See In re Darvocet, Darvon & Propoxyphene Prods. Liab. Litig.*, 780 F. Supp. 2d 1379, 1381 (J.P.M.L. 2011) ("Because potential plaintiffs and putative class members will reside in every corner of the country and defendants are located in several states, the location of the currently filed cases is not a particularly significant factor in our decision.").

Nor can it be said that the pending California cases — *Carter*, *Herrera*, *Hexum*, and *Saavedra* — have yet proceeded to a posture where the two judges Plaintiffs propose would have had an opportunity to gain meaningful substantive exposure on the merits of these suits. To the contrary, due to the posture of the *Carter*, *Herrera*, and *Hexum* cases, Chief Judge King has addressed only initial scheduling and has not had occasion to make any substantive merits rulings or address any discovery issues in the three cases consolidated before him. And Judge Wilson has been involved only in the class action, not any individual injury cases, and his

involvement has focused nearly exclusively on the issues of class certification — issues that by definition will not be implicated in the individual product liability suits.

3. This Panel should select a transferee court with caseload statistics more favorable than the Central District of California.

The Central District of California has no fewer than 18 pending MDLs.[8] Only two districts in the country — New Jersey and the Southern District of New York — have more. This fact alone makes the Central District of California an undesirable transferee district. *See, e.g.*, *Trasylol*, 545 F. Supp. 2d at 1358 (identifying the district's "relatively low number of MDL dockets" favorably in selecting a transferee district); *see also In re Camp Lejeune*, 763 F. Supp. 2d at 1382 (selecting transferee district that "does not have many MDLs on its docket"). In contrast to the Central District of California, the Middle District of Florida, Northern District of Ohio, and Northern District of Georgia, which Lilly proposes as alternate possibilities, have four, seven, and nine pending MDLs, respectively.

4. A judge with experience in pharmaceutical products liability MDL actions would be best positioned to oversee this litigation.

In assigning MDLs to transferee courts, this Panel also looks to judges with specialized experience in the type of litigation and subject matter in question. *See In re Pradaxa Products Liability Litigation*, 883 F. Supp. 2d 1355, 1356 (J.P.M.L. 2012) (selecting "an experienced MDL judge" who had previously "deftly presided over . . . another large pharmaceutical products liability litigation"); *see also In re Mirena*, 938 F. Supp. 2d at 1358 (J.P.M.L. 2013) (transferring to an "experienced transferee judge"); *In re Plavix Marketing, Sales Practices and Products Liab. Litig.*, 923 F. Supp. 2d 1376, 1380 (J.P.M.L. 2013)

[8] MDL Statistics Report, Pending MDLs (8/15/14), http://www.jpml.uscourts.gov/sites/jpml/files/Pending_MDL_Dockets_By_District-August-15-2014.pdf (last visited September 8, 2014).

(transferring to a judge who had previously "served as a transferee judge in three MDLs"). Assigning an MDL to a judge with such experience is particularly appropriate where, as here, the subject actions concern the products of a niche and highly-specialized industry.

In the Middle District of Florida, where the *Bhoge* action is pending, Lilly has identified Judge James S. Moody as a possible MDL judge. Since 2004, Judge Moody has presided over *In re Accutane Prods. Liab. Litig.*, MDL No. 1626, a complex pharmaceutical products liability MDL which currently has only three actions pending, down from a historical total of 122. In the Northern District of Ohio, where the *Mayes* action is pending, Lilly has identified Judge James S. Gwin as a possible MDL judge. Judge Gwin does not currently preside over any MDLs, and recently presided over *In re Meridia Prods. Liab. Litig.*, MDL No. 1481, another complex pharmaceutical products liability MDL. Finally, in the Northern District of Georgia, where the *Couch* action is pending, Lilly submits that Judge Timothy C. Batten, to whom *Couch* is currently assigned, could ably handle a Cymbalta MDL. Judge Batten currently presides over MDL No. 2089, *In re Delta/AirTran Baggage Fee Antitrust Litig.*, which has no pending actions.

All three locations present no transportation concerns. Judge Moody sits in Tampa; Judge Gwin sits in Cleveland; and Judge Batten sits in Atlanta. All three cities have major airports with direct flights to and from Indianapolis and the cities where the lead plaintiff and defense counsel reside.

III. CONCLUSION

For the foregoing reasons, Plaintiffs' motion for centralization and transfer to the Central District of California should be denied in its entirety. In the alternative, the Panel should centralize the subject actions in either the Middle District of Florida, the Northern District of Ohio, or the Northern District of Georgia.

Respectfully submitted,

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BEFORE THE JUDICIAL PANEL
ON MULTIDISTRICT LITIGATION

In re: Cymbalta Products Liability Litigation — MDL No. 2576

CERTIFICATE OF SERVICE

In compliance with Rule 4.1(a) of the Rules of Procedure of the United States Judicial Panel on Multidistrict Litigation, I certify that on September 9, 2014 I caused a true and correct copy of the foregoing Defendant Eli Lilly and Company's Response to Plaintiffs' Motion Pursuant to 28 U.S.C. § 1407 to Transfer Related Actions for Coordinated Pretrial Proceedings to be filed electronically through the CM/ECF system, which caused a Notice of Electronic Filing to the following individuals:

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DATED: September 9, 2014
Washington, D.C.

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Exhibit D

BEFORE THE UNITED STATES JUDICIAL PANEL
ON MULTIDISTRICT LITIGATION

In re: Cymbalta (Duloxetine) Products Liability Litigation — MDL No. 2576

REPLY IN SUPPORT OF PLAINTIFFS' MOTION PURSUANT TO 28 U.S.C. § 1407 TO TRANSFER RELATED ACTIONS FOR COORDINATED PRETRIAL PROCEEDINGS IN THE CENTRAL DISTRICT OF CALIFORNIA

Eli Lilly and Company ("Lilly") opposes centralization for two flawed reasons. First, Lilly claims that this litigation is predominated by individual issues associated with the learned intermediary defense—an affirmative defense inherent in *all* pharmaceutical personal injury lawsuits—and that centralization would undermine its ability to assert that defense. Second, Lilly claims that the number of cases at issue do not warrant centralization and that voluntary coordination among the parties is a better approach. Neither of these reasons are valid.

First, centralization would not undermine the ability of Lilly to raise (if applicable) a learned intermediary defense. Pharmaceutical Multidistrict Litigations ("MDLs") have successfully dealt with the learned intermediary defense for decades. In fact, an MDL would actually facilitate litigation of the issue. Pretrial discovery can be coordinated as appropriate and the legal doctrine can be *consistently* applied. Having a single court evaluate the defense, as opposed to dozens of different courts, directly promotes the purposes of 28 U.S.C. § 1407.

Second, Lilly's belief that voluntary coordination is preferable to formal centralization is misplaced. As it stands, trying to voluntarily coordinate the related actions would, itself, be untenable. So far, for the *six* cases that have actually had significant discovery, pretrial discovery has been contentious. Despite Lilly's rosy claims of cooperation, few issues have proceeded without court intervention. Taking into account the other related cases, the fact that multiple law firms are now involved, and the near certainty of hundreds if not thousands of cases

that are going to be filed, voluntary coordination is not a workable solution. The only way these related cases, and the ones in the pipeline, will be resolved without a colossal duplication of effort, is to centralize the proceedings before a single court, preferably the Honorable Stephen V. Wilson in the Central District of California.[1]

Lilly's resistance to centralization in the Central District of California makes little sense. Any argument that the Central District of California, before Judge Wilson, is "too far" is belied by Lilly's desire to litigate seven of the related cases in that very court should the Panel deny this motion. Placing the MDL before some other judge, who has no familiarity with this litigation, would not be efficient or serve the purposes of 28 U.S.C. § 1407. Centralization of these related actions before Judge Wilson in the Central District of California will ensure that these cases are efficiently and fairly adjudicated and spare an already over-worked judiciary.

EXPANDING CYMBALTA WITHDRAWAL LITIGATION

Since this motion was filed, numerous attorneys have reached out to Movants' counsel, indicating that they are also pursuing Cymbalta withdrawal claims. *See* Declarations attached as Exhibits 1-6. Based on the information that has been provided, it is clear that a large wave of Cymbalta Withdrawal cases is on the horizon. In total, over 6,012 potential claimants have inquired about pursuing Cymbalta Withdrawal claims. *Id.* (adding up numbers in declarations). And, as it stands, over 1,191 of those cases are actively being pursued. Considering that this is just a selection of the law firms pursuing these cases, the scale of this litigation will easily match that seen in the similar *In re Paxil* withdrawal litigation (over 3,000 claims). Establishing an MDL *before* these large numbers of claims are filed will save the parties and the judiciary significant expense by ensuring they are managed and coordinated uniformly from the start.

[1] All of the cases that were before the Honorable George H. King in the Central District of California were recently transferred to Judge Wilson. Thus, Judge Wilson is the best choice for a transferee court.

ARGUMENT

I. Common Issues Raised By this Litigation Are Ideally Suited for Centralization.

The first issued raised in Lilly's opposition focuses on whether there are common issues of fact among the related actions. Lilly asserts, amazingly, that "[t]here are no disputed 'common' questions that would justify an MDL: here there is no dispute about the risk that Cymbalta, like every other antidepressant in its class, can lead to certain side effects upon the discontinuation of the medicine[.]" Lilly Opp. at 1. According to Lilly, Cymbalta withdrawal litigation "does not present questions of *general causation*[.]" *Id.* at 11. And yet, in the very same brief, Lilly argues at length that the label for Cymbalta was *not* misleading and that Lilly did *not* fail to warn consumers about the risk of withdrawal. *Id.* at 4-8. Indeed, Lilly states that "the core allegation in Plaintiffs' complaints is that Lilly's warning to physicians is somehow misleading" and then, in the *next sentence*, attempts to rebut that "core allegation." *Id.* at 6.

Lilly's inconsistent position belies the truth. From the beginning, Lilly has vigorously defended the Cymbalta label, arguing that the label *does* adequately warn about the risk of Cymbalta withdrawal.[2] And, the question of a label's adequacy is, by definition, an issue of *general causation* in a failure to warn case. As this Panel noted in deciding to centralize similar claims involving Paxil—an MDL that was managed successfully by Movants' counsel—whether a drug manufacturer misrepresented a side effect in the labeling is a common issue of fact:

> Common factual questions arise because all actions focus on alleged side effects of Paxil, a widely-prescribed anti-depressant drug, *and whether defendants knew of these side effects and either concealed, misrepresented or failed to warn of them.* Centralization under Section 1407 is thus necessary in order to avoid duplication of discovery, prevent inconsistent or repetitive pretrial rulings, and

[2] Movants allege that the Cymbalta label, with its "greater than or equal to 1%" language is very misleading considering Lilly's *own* clinical trials indicate that the risk is, at least, 44.3%. Indeed, the Cymbalta warning label in other countries clearly discloses the 44.3% risk, but the U.S. one does not.

conserve the resources of the parties, their counsel and the judiciary.

In re Paxil Products Liab. Litig., 296 F. Supp. 2d 1374, 1375 (J.P.M.L. 2003) (emphasis added).

There are numerous issues of general liability and causation that are common to all the related actions, as Lilly concedes. Lilly Opp. at 10 ("Lilly does not dispute that the subject actions share some common issues."). And, it is difficult to argue that centralization to coordinate these pretrial issues would not serve the purposes of 28 U.S.C. § 1407.

First, centralization will "promote the just and efficient conduct of" these related actions. 28 U.S.C. § 1407(a). One court, as opposed to potentially hundreds, would: (1) determine the permissible scope of discovery, i.e., whether Plaintiffs are entitled to documents related to the research and marketing of other Lilly products; (2) enter important pretrial orders such as protective orders; (3) conduct a *Daubert* analysis of the parties' experts; (4) determine whether punitive damages are appropriate; and, as discussed below, (5) consider Lilly's affirmative defenses, i.e., preemption, learned intermediary, statute of limitations, etc. Having potentially hundreds of different courts tackle these complicated and important issues separately would lead to inconsistent rulings and waste judicial resources.

Second, centralization would serve "the convenience of parties and witnesses." 28 U.S.C. § 1407(a). Having *one* forum from which the parties can resolve all pretrial issues one time, as opposed to re-litigating these issues over and over among different courts would be, despite Lilly's assertions otherwise, convenient for *both* parties. Having *one* set of local rules, *one* governing protective order, *one* scheduling order, *one* ruling on the permissible scope of discovery, *one* ruling on the general applicability of the learned intermediary doctrine, *one* ruling on the issue of preemption, and *one Daubert* hearing for each expert would streamline the

litigation process and save countless hours of duplicative litigation.[3]

II. Any Individual Issues Associated with the Learned Intermediary Defense Are Best Resolved in the MDL Setting, Not Separately / Inconsistently Among Hundreds of Different Courts.

Lilly's primary opposition to pretrial coordination rests on the incorrect assumption that centralization would prevent Lilly from asserting a learned intermediary defense, and create "a 'Field of Dreams' that attracts a swath of meritless claims that can be shielded from individualized discovery[.]"[4] Lilly Opp. at 3. Rhetoric aside, even if the learned intermediary defense were, as Lilly asserts, the most important issue in this litigation—and it is not—there is absolutely no indication that centralization would prevent the learned intermediary issue from being resolved. In fact, centralization would *streamline* it.

First, the existence of a learned intermediary defense does not, by itself, prevent centralization. The learned intermediary defense is a part of *every* failure to warn lawsuit involving a pharmaceutical product. Essentially, the learned intermediary defense provides that a drug manufacturer is not liable for failing to warn a patient about a specific risk associated with a prescription drug provided the manufacturer properly warned the prescriber of that risk. *See, e.g.*, *Saavedra v. Eli Lily & Co.*, 2:12-CV-9366-SVW-MAN, 2013 WL 6345442, *3 (C.D. Cal. Feb. 26, 2013) (Judge Wilson discussing the application of the learned intermediary defense to Cymbalta Withdrawal consumer protection claims). Thus, "upon proof that the drug manufacturer adequately warned prescribing physicians about potential side-effects, the manufacturer is immune from liability." *Id.* However, despite the fact that this defense applies to *every* personal injury claim involving a pharmaceutical product, this Panel routinely

[3] Lilly is already familiar with litigating in the Central District of California, having litigated the *Saavedra*, *Carter*, *Herrera*, and *Hexum* cases in the Central District of California for over a year a half.

[4] Notably, the likelihood that the creation of an MDL will entice the filing of additional claims is not a factor that the Panel considers under 28 U.S.C. § 1407. Lilly's suggestion that these claims are "meritless" is an empty assertion. The merit of these Cymbalta withdrawal actions is not the subject of this motion. Movants are confident, however, that these underlying claims have a "greater than or equal to 1%" chance of being successful.

centralizes products cases involving pharmaceutical products.[5] And this is not surprising—a single affirmative defense should not dictate this Panel's decision to coordinate pretrial matters.

Second, nothing prevents Lilly from raising a learned intermediary defense in an MDL context. MDL courts routinely consider issues associated with the learned intermediary defense as part of a coordinated proceeding. *See, e.g.*, *In re Norplant Contraceptive Products Liab. Litig.*, 215 F. Supp. 2d 795, 806-23 (E.D. Tex. 2002); *In Re Yasmin & Yaz (Drospirenone) Mktg., Sales Practices & Products Liab. Litig.*, 692 F. Supp. 2d 1012, 1019-21 (S.D. Ill. 2010); *In re Fosamax Products Liab. Litig.*, 807 F. Supp. 2d 168, 186-87 (S.D.N.Y. 2011). Indeed, Lilly, itself, was able to raise its learned intermediary defenses in the *In re Zyprexa* litigation. *See In re Zyprexa Products Liab. Litig.*, 489 F. Supp. 2d 230, 265, 267, 269, 280-81 (E.D.N.Y. 2007); *In re Zyprexa Products Liab. Litig.*, 649 F. Supp. 2d 18, 32-33 (E.D.N.Y. 2009); *In re Zyprexa Products Liab. Litig.*, 277 F.R.D. 243, 249-51 (E.D.N.Y. 2011). There is absolutely no support for Lilly's assertion that centralization would shield claims from Lilly's learned intermediary defense. The "transferee court can employ any number of pretrial techniques—such as establishing separate discovery and/or motion tracks—to efficiently manage this litigation." *In re Lehman Bros. Holdings, Inc., Sec. & Employee Ret. Income Sec. Act (ERISA) Litig.*, MDL2017, 2009 WL 413602 (Feb. 9, 2009). A transferee court can take whatever actions it believes are necessary to address Lilly's learned intermediary defense. *See In re Vioxx Products Liab. Litig.*, 360 F. Supp. 2d 1352, 1354 (J.P.M.L. 2005) (discussing the ability of transferee court to coordinate case specific issues in pharmaceutical context).

Third, as this litigation continues to expand, having the learned intermediary defense adjudicated by a single court overseeing all aspects of pretrial litigation is better than having

[5] Moreover, before any learned intermediary defense can be evaluated, the deficiencies in the labeling must be evaluated. It would be impossible to determine whether a prescriber was properly warned without evaluating the merits of a drug's labeling. This question, i.e., the sufficiency of the label, is a common question of fact.

hundreds of different courts evaluate the issue separately. A single forum ensures that the learned intermediary defense is, one way or the other, consistently applied. It also saves a considerable amount of judicial resources and duplicative briefing required to bring each court up-to-speed on the various aspects of this litigation. And, for those many cases that survive the learned intermediary defense or at least raise a triable issue of fact, an ongoing MDL will ensure that discovery related to common issues of fact and law are simultaneously developed.

III. Voluntary Coordination Is Not a Viable Option.

Lilly argues that there is no need for an MDL because counsel for Lilly and counsel for many of the related actions can voluntarily coordinate pretrial discovery. Lilly cites to the fact that there has been voluntary cooperation regarding pretrial discovery among counsel over the last sixteen months for six Cymbalta withdrawal cases.[6] However, voluntarily coordinating just six cases in different courts has, itself, proven difficult. Adding an additional dozen cases to that "voluntary cooperation mix" would exponentially increase the difficulty of coordinating pretrial matters and likely destabilize the situation. And, when those cases begin to number in the hundreds or thousands and involve different counsel and many different courts, voluntary coordination is simply not a viable option. Lilly attempts to rebut this fact by suggesting that the possibility of hundreds of additional cases "warrants a skeptical eye." Lilly's Opp. at 14. Hardly. As demonstrated by the various declarations attached to this filing, over a thousand Cymbalta Withdrawal cases are actively being investigated by different law firms.

Lilly's argument that "the sheer number of cases filed by Movants' Counsel does not justify consolidation" is simply incorrect. In *In re Paxil*, this Panel centralized *twelve* nearly identical antidepressant withdrawal cases in the Central District of California. 296 F. Supp. 2d at

[6] Lilly's suggestion that "it is unlikely that much if any additional discovery will be required from Lilly" is baseless. As it stands, the 1.8 million pages of documents produced are woefully deficient.

1375. This motion, however, seeks to centralize 30 cases (adding in those cases filed by other firms after this motion was submitted). This Panel has consistently refused to limit its ability to create an MDL to a specific number of claims. The sheer number of cases is not the issue, particularly when several hundred additional claims are in the pipeline.

Lilly also complains that Movants' counsel is simply trying to "manufacture an MDL." Lilly Opp. at 14. And, despite Lilly's pejorative slant, there is some truth to this. There is no doubt that Movants' counsel represents many (although not all) of the plaintiffs in the related actions and that the timing of this motion coincided with the filing of about a dozen cases around the country. Indeed, there is no question that Movants' counsel wants an MDL formed—that is, after all, the purpose of this motion. But, the *reason* Movants want an MDL comports with the purposes of 28 U.S.C. § 1407, namely, to streamline similar litigation and avoid duplication of work and judicial resources. This motion is born out of *pragmatism*, not gamesmanship. There are already a sufficient number of cases to warrant an MDL and the likelihood of many more cases is a certainty. Litigating these similar cases in different courts would be a waste of judicial resources and would invariably inconvenience the parties. And, as demonstrated by the success of *In re Paxil*, an MDL that was created with only twelve withdrawal cases on file, but ballooned to over 3,000. Movants are not asking for anything this Panel has not already allowed. Indeed, the success of *In re Paxil* speaks to the value centralization can play in resolving these cases.

IV. Centralization within the Central District of California Is Appropriate.

Recently, all the pending cases within the Central District of California—*Herrera*, *Hexum*, *Caporale*, *Hollowell*, *Barrett*, and *O'Shea*—were transferred from the Honorable George H. King to the Honorable Stephen V. Wilson, the judge who has been presiding over the *Saavedra* class action since 2012. This means that, along with *Saavedra*, there are seven pending personal injury claims before Judge Wilson—the judge who has the most experience

and familiarity with Cymbalta Withdrawal litigation.[7] Clearly, Judge Wilson is the most logical choice to oversee any Cymbalta Withdrawal MDL. *In re Land Rover LR3 Tire Wear Products Liab. Litig.*, MDL 2008, 2009 WL 467572 (Feb. 23, 2009) ("The Central District of California is an appropriate transferee forum because the first-filed and most procedurally advanced actions are pending there. . . [S]ubstantial benefits arise by assigning the litigation to Judge Guilford, who has gained familiarity with this litigation by presiding over some of the actions[.]").

Lilly's reasons against centralization in the Central District of California are unavailing. *First*, Lilly states that centralizing these proceedings in the Central District of California would be inconvenient for Lilly and Lilly's national counsel because they are based in Indianapolis, Indiana, and Washington, D.C. Lilly Opp. at 15-16. This argument, however, is inconsistent with Lilly's general opposition to centralization. As it stands, the related actions are pending in 22 district courts all over the country. Absent centralization, these related actions will be subject to case-specific scheduling orders, discovery schedules, motions practice, etc. It is contradictory for Lilly to be willing to litigate these 30 actions in different courts all over the United States and then object to the convenience of centralizing all the cases in the Central District of California—a forum that, absent centralization, Lilly would be forced to litigate in anyway. Lilly cannot have it both ways. If decentralized litigation and voluntary coordination is convenient, as Lilly argues, then surely centralization in a single forum is *more* convenient.

Second, Lilly argues that the Central District of California has no particular connection to this litigation. Lilly Opp. at 17-18. In the sense that this litigation will involve plaintiffs from all over the United States, that is correct. No single district court has a "special" connection with this litigation. However, the Central District of California, and in particular Judge Wilson, has a

[7] Although *Saavedra* is primarily a consumer class action, Jennifer Saavedra is also seeking non-class personal injury claims against Lilly as part of the lawsuit. The *Carter* case was recently voluntarily dismissed.

direct relationship with this litigation, having the largest number and most developed cases.

Finally, Lilly claims that the Central District of California is not a suitable transferee court because it has 18 pending MDL proceedings. Lilly Opp. at 18. This argument, however, ignores two salient facts. First, the Central District of California is the largest district court in the country with thirty-eight district judges and twenty-five magistrate judges.[8] Second, although there are numerous pending MDLs in the Central District of California, none are presently before Judge Wilson. This is *not* a situation where a single court is being overwhelmed by MDLs.

V. Lilly's Proposed Alternative Forums Are Unfamiliar with this Litigation.

Lilly proposes the Honorable James S. Moody in the Middle District of Florida, the Honorable James S. Gwin in Northern District of Ohio, and the Honorable Timothy C. Batten in the Northern District of Georgia as possible alternative transferee courts. Judges Moody and Gwin, however, have no Cymbalta Withdrawal cases before them. And, Judge Batten, while assigned one Cymbalta Withdrawal case, has taken no action as the complaint has not even been served yet. Thus, centralization before these three courts would amount to a reset button on all Cymbalta Withdrawal litigation. Each judge would need to be familiarized with this litigation, rehear the parties' arguments on various discovery matters, and, essentially, start from scratch—issues that could be avoided if the Panel centralized these cases before Judge Wilson.

CONCLUSION

Based on the foregoing, Movants respectfully request that the Panel order coordinated pretrial proceedings for Cymbalta withdrawal injury cases and transfer all such pending and future cases to the Central District of California before the Honorable Stephen V. Wilson.

DATED: October 3, 2014
Los Angeles, California

BAUM, HEDLUND, ARISTEI & GOLDMAN, P.C.

[8] *See* FAQs about Judges' Procedures and Schedules (10/3/2014), http://court.cacd.uscourts.gov/CACD/JudgeReq.nsf/FAQs+about+Judges%27+Procedures+and+Schedules?OpenView.

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Heather Laica-Bhoge and Alberto Bhoge
Douglas Gollin and Lynn Gollin
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Johnson Fairbanks
Eric McCabe
Jesse McDowell
Elizabeth Whitworth
Mark Williams
Shelly Harris
Gregory Mayes
Donna Loux
Melissa Rossero
Karen Wagner and Marvin Wagner
Adam Streeter
Karen Boling and Joseph Boling

Exhibit E

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January 7, 2015

VIA E-MAIL ONLY

Phyllis A. Jones, Esq.
Michael X. Imbroscio, Esq.
COVINGTON & BURLING LLP
1201 Pennsylvania Avenue, NW
Washington, DC 20004-2401

Dear Phyllis,

This letter follows our recent discussions concerning the future of Cymbalta withdrawal injury litigation generally. We write to you collectively as counsel for most, if not all, of the currently filed cases.

First, when we last spoke as a group, you advised that we should expect Lilly to propose a plan for the coordination of Cymbalta injury cases that are currently in suit. We await your proposal and look forward to discussing options with you.

Second, as we have represented to both Lilly and the JPML, our firms have amassed hundreds—indeed, now thousands—of potential Cymbalta withdrawal plaintiffs. And we assure Lilly that our clients are resolved to move forward with this litigation even in the absence of a formal MDL. In recent weeks, we have filled several suits to preserve our clients' rights and will continue to file these matters as needed going forward. However, in light of Mr. Imbroscio's representation to the JPML about engaging in informal coordination, we would like to explore the prospect of mass tolling. The purpose of such an endeavor would be to streamline this litigation without burdening the judiciary (yet) with thousands of different suits, consistent with the views expressed by the JPML about the viability of informal coordination. While this letter is not intended to set forth all of the particulars of such an arrangement, we propose the following broad strokes to start the discussion:

1. For all of our clients not currently in suit, a tolling agreement through December 31, 2015;

2. In exchange for mass tolling, we provide certain basic information about each claimant and necessary HIPAA releases for the pre-suit collection of medical and pharmacy records; and

3. To allow the parties time to negotiate all of the particulars, an unqualified agreement by Lilly to toll cases currently under contract for 45 days (or any case that comes under contract during those 45 days) starting on the day Lilly agrees.

We believe tolling along these lines, along with reasonable pre-suit access to medical records, allows both parties to engage in the sort of informal coordination needed to resolve this massive litigation outside of a formal MDL. Please let us know by the close of business on January 16, 2015 whether Lilly is interested in negotiating such an agreement, and if so, whether it will consent to the unqualified 45-day tolling set forth above.

Sincerely,

BAUM HEDLUND ARISTEI & GOLDMAN, P.C.

By: /s/ Michael L. Baum
Michael L. Baum, Esq.

KELLER ROHRBACK L.L.P.

By: /s/ Michael D. Woerner
Michael D. Woerner, Esq.

POGUST BRASLOW & MILLROOD, LLC

By: /s/ Harris L. Pogust
Harris L. Pogust, Esq.

Exhibit F

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BY ELECTRONIC MAIL

January 13, 2015

Michael L. Baum, Esq.
Baum Hedlund Aristei & Goldman P.C.
12100 Wilshire Boulevard, Suite 950
Los Angeles, CA 90025-7114

Re: Cymbalta DEAE Litigation - January 7 Tolling Proposal

Counsel:

This letter responds to your January 7, 2015 correspondence proposing that the parties enter a tolling agreement for all clients of Baum Hedlund Aristei & Goldman PC, Keller Rohrback L.L.P., and Pogust Braslow & Millrood, LLC not currently in suit. On behalf of Lilly, we respectfully decline this offer.

As we indicated previously, we are happy to work with plaintiffs' counsel to coordinate across the currently-filed cases, as well as any cases that may be filed going forward. We have transmitted to you today under separate cover our proposal for certain coordination activities that we would propose that the parties undertake in the near term.

Sincerely,

Phyllis A. Jones

cc: R. Brent Wisner, Esq.
Michael D. Woerner, Esq.
Harris L. Pogust, Esq.

Exhibit G

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January 22, 2015

VIA E-MAIL ONLY
Phyllis A. Jones, Esq.
Michael X. Imbroscio, Esq.
COVINGTON & BURLING LLP
1201 Pennsylvania Avenue, NW
Washington, DC 20004-2401

Re: Proposal for Coordination of Cymbalta Withdrawal Personal Injury Claims

Counsel:

Thank you for your letter dated January 13, 2015. This is our response to your Coordination Proposal for the Cymbalta withdrawal personal injury litigation.

I. Effect of Lilly's Refusal to Enter Tolling Agreements

In light of Lilly's refusal to accept any tolling, we will continue to file cases to preserve our clients' rights. However, having different cases proceeding on different schedules in a multitude of different courts around the country is not efficient and creates case scheduling conflicts—a fact already evident in trying to coordinate a fraction of the cases that eventually will be filed. We stress, again, there are thousands of cases in the pipeline. Absent some simplification in the litigation process, this litigation will spiral out of control.

II. Plaintiffs' Third Proposal to Coordinate the Litigation

Lilly objected first to our request for an MDL and second to our request for tolling agreements. We now plan to file cases within the Southern District of Indiana, the district where Lilly is headquartered. This will allow coordination of cases in a *single* district in consideration of the volume of cases on the horizon.

To further coordinate, we propose transferring existing cases that have not yet been litigated in any meaningful way (i.e., not *Herrera*, *Hexum*, or *Seagroves*) to the Southern District of Indiana pursuant to 28 U.S.C. § 1404(a). We plan to file these motions next week, so we would appreciate a response from Lilly by Friday, January 23, 2015 – i.e., please advise if Lilly will join or not oppose motions to transfer existing cases to the Southern District of Indiana.

In the alternative, we would also be willing to voluntarily dismiss without prejudice these cases and re-file them in the Southern District of Indiana, provided Lilly agrees that any time during which the cases were filed and until they are re-filed (i.e., two or three weeks) are tolled for statute of limitations purposes—this would not waive or affect any statute of limitations challenges that presently exist. This latter approach would ensure that all the cases are centralized in the Southern District of Indiana and would not hinge transfer on each court's particular ruling on the motion to change venue.

III. Identification of Counsel for Litigation-Wide Correspondence

We cannot designate a single person to speak for all cases at this time, as there are simply too many moving parts and new cases will continue to be filed / served in the coming months. For now, please include R. Brent Wisner, Michael Baum, Michael Woerner, Harris Pogust, Matthew Leckman, and Steven Stein on emails involving global discovery issues.

IV. Document Production to Date

We appreciate Lilly's willingness to make available those documents that have been produced in prior litigation, subject to a protective order, and Lilly's acknowledgment that additional discovery will be forthcoming.

Documents. We have reviewed Lilly's written discovery responses and document productions in the previously filed cases and have found the productions to be deficient. A comparison of Plaintiffs' discovery requests, Lilly's written responses and the charts Lilly produced identifying the documents responsive to each request reveal that, in many instances, Lilly only produced "examples" of the requested documents. In a number of instances, the documents identified are in no way responsive to the actual request. Indeed, although an essential part of any pharmaceutical litigation is the NDA, it appears Lilly hasn't even produced the original NDA for Cymbalta, and only bits and pieces of the sNDAs for a few subsequent indications. We also found a pdf of the index to the Electronic Common Technical Document (eCTD) for Chronic Pain and GAD in Lilly's document production, but as I'm sure you are aware, a pdf of the index of an *electronic* submission is completely useless to us. We have obtained eCTDs (in electronic format) in other litigation and do not understand why Lilly did not produce the eCTDs for all indications in these earlier cases.

In addition, for many of Plaintiffs' requests, Lilly limited its response to a specific client. And, despite repeated requests for internal communications about Lilly's development of the Cymbalta label, documents reflecting Lilly's internal communications are nearly non-existent. The 2.7 million pages of documents Lilly boasts about is simply a *selection* of documents, many of which are duplicates of innocuous documents, fragmented and far from complete. These are only some of the deficiencies we have identified.

The only practical way to proceed in these recently filed cases is to re-issue a new set of document requests to Lilly. However, we plan to engage in this process in a coordinated manner and, hopefully, complete it on behalf of all the cases.

Depositions. We appreciate Lilly making depositions from prior cases available, subject to a protective order, for this litigation. Regarding cross-noticing, we do not anticipate this being a problem going forward, but we do not speak for all plaintiffs who might file cases. We can certainly discuss this further as we reach that stage in the litigation.

V. Medical Authorizations and Medical Record Retention

As you know, our clients hold a privilege over the confidentiality of their medical records. The waiver of that privilege must be narrowly tailored, particularly in the context of an adversarial proceeding such as a lawsuit where extraneous issues could be subject to inadvertent disclosure. A waiver of that privilege though a "blanket" authorization—without any substantive or temporal limits—is not appropriate, particularly in these relatively straight-forward Cymbalta-withdrawal cases. Moreover, many medical facilities and physicians will not accept blanket waivers and often require use of their specific authorizations. Thus, use of a blanket waiver is not practicable.

That said, we understand that Lilly has the right to engage in *some* discovery related to our client's medical treatment. Thus, we propose that Lilly issue relevant doctor-specific and/or facility-specific authorizations and we will have our clients execute them as we deem appropriate. Without any restrictions, the process of medical record collection will become needlessly burdensome, expensive and invasive, and the probative value of such discovery will not outweigh the expense and invasion of privacy inherent in such a process.

Regarding Lilly's proposal to share the costs of medical record collection, we respectfully decline. Our clients will gladly produce all discoverable documents in their possession for free—even though our clients incurred costs in collecting them—but they will not foot a bill incurred by Lilly in collecting a third-party's documents or records. We will, however, pay for any reasonable copying costs associated with sending a copy of the records Lilly obtains to Plaintiff.

Sincerely,

BAUM, HEDLUND, ARISTEI & GOLDMAN, P.C.

By: /s/ Michael L. Baum
Michael L. Baum, Esq.

POGUST BRASLOW & MILLROOD, LLC

By: /s/ Harris L. Pogust
Harris L. Pogust, Esq.

KELLER ROHRBACK L.L.P.

By: /s/ Michael D. Woerner
Michael D. Woerner, Esq.

KNOX RICKSEN, LLP

By: /s/ Steven B. Stein
Steven B. Stein, Esq.

Exhibit H

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BY ELECTRONIC MAIL

January 27, 2015

R. Brent Wisner
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Re: Cymbalta DEAE Litigation - Coordination Matters

Dear Counsel:

We are in receipt of your January 22, 2015 letter. This letter responds to the issues raised there.

I. Plaintiffs' Proposal to Transfer Pending Cases

Lilly respectfully declines to join plaintiffs' motion to transfer any of the pending discontinuation matters to the Southern District of Indiana. Those cases have proceeded through responsive pleadings and, in certain instances, preliminary discovery matters in the venues of plaintiffs' choosing. Having elected to file and serve the pending cases in their current venues, you have offered no justification for the transfer of those cases at this juncture. Moreover, transfer of those matters would materially impair the ability of the parties to secure live trial testimony from some of the core witnesses at issue, including any healthcare professionals who had a role in plaintiffs' care. For the latter reason, Lilly would also oppose the filing of suits in the Southern District of Indiana by plaintiffs who are not resident in that forum and whose claims arise from a nucleus of facts centered outside of the Southern District of Indiana.

As we have made clear in our earlier correspondence, Lilly is committed to coordinating with counsel across the litigation to minimize duplication of effort and make use of the considerable discovery undertaken to date. We have done so, including in the filing of Lilly's responsive pleadings, service of its initial disclosures, ongoing discovery discussions as obligated under Fed. R. Civ. P. 26(f), and our agreement that all prior discovery would be made available across the litigation subject to the entry of an appropriate protective order. Lilly's decision not to enter into tolling agreements for the additional, unfiled cases you have described in your earlier correspondence is not inconsistent with that overarching goal. In the event that those potential claimants elect to file their claims, Lilly is amenable to extending the same coordination proposal to the relevant counsel and fully committed to working with counsel to achieve the same efficiencies we have aimed to secure in the pending cases.

II. Lilly's Document Production Date

Please note the following with respect to the matters raised in your January 22 letter regarding Lilly's document production to date.

First, in response to your request to convene a call regarding certain e-discovery matters, we asked by email dated January 21, 2015 that you provide us with a summary of the "technical issues" you have encountered in Lilly's production so that we could identify the appropriate individual to participate in any call with the relevant individuals working with plaintiffs' counsel. We have not heard further from you on that, but, as we have already explained, we are willing to participate in such a call.

Second, as previously indicated, Lilly is agreeable to making its document production available across the cases, subject to the entry of an agreed-upon protective order. We have still not heard from you on the draft protective order that we provided on January 13, 2015.

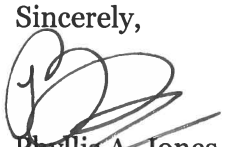
Third, as to your suggestion that plaintiffs intend to "re-issue a new set of document requests to Lilly," Lilly will, of course, review carefully and provide objections and responses appropriately. However, given Lilly's agreement to make its existing production available across the litigation — and the JPML's determination in its December 10, 2014 Order that "most, if not all, of the common discovery has already taken place" and that discovery to date has been "substantial" — Lilly would object to efforts to conduct discovery anew on the same topics on which document production has been made to date.

III. Medical Authorizations and Records Retention

We provided to you with our January 13 letter, a draft medical records authorization that tracks the authorization used without objection in the earlier-filed Cymbalta discontinuation matters. We have provided the same authorization in connection with Lilly's written discovery served to date. If you have proposed edits to the authorizations Lilly has provided — including any suggested "substantive or temporal limits" — we ask that you raise those issues promptly. If plaintiffs do not raise any issues, we will expect the authorizations to be executed and will, as necessary, seek relief from the relevant courts to secure authorization to retrieve the records to which Lilly is entitled. We are happy to work with plaintiffs' counsel in refining the authorizations where necessary, but we do not believe it is appropriate for plaintiffs to invoke unspecified objections to the proposed authorization as a basis for delaying discovery.

Finally, we have no objections, of course, to your decision not to share the cost of medical records collection. Based upon your letter, we will assume that plaintiffs will undertake their own efforts to collect records and decline your proposed alternative arrangement in which Lilly bears the costs of records collection and plaintiffs simply pay copy costs.

Sincerely,



Phyllis A. Jones

Exhibit I

UNITED STATES JUDICIAL PANEL
ON
MULTIDISTRICT LITIGATION

IN RE:	)	No. 2576
	)	
CYMBALTA (DULOXETINE)	)	
PRODUCTS LIABILITY	)	Charleston, SC
LITIGATION	)	December 4, 2014

TRANSCRIPT OF PROCEEDINGS
BEFORE U.S PANEL ON MULTIDISTRICT LITIGATION

Hon. Sara S. Vance, Chair
United States District Court
Eastern District of Louisiana

Hon. Marjorie O. Rendell
United States Court of Appeals
Third Circuit

Hon. Lewis A. Kaplan
United States District Court
Southern District of New York

Hon. R. David Proctor
United States District Court
Northern District of Alabama

Hon. Catherine D. Perry
United States District Court
Eastern District of Missouri

(Panel convened at the Charleston United States Courthouse, Charleston, South Carolina)

APPEARANCES:

For Thomas Seagroves, et al.:
Mr. Brent Wisner
Baum Hedlund
Aristei & Goldman, P.C.
12100 Wilshire Blvd.
Suite 950
Los Angeles, CA 90025

For Eli Lilly & Company:
Mr. Michael Imbroscio
Covington & Burling LLP
One City Center
850 Tenth Street NW
Washington, DC 20001

Official Court Reporter:
Amy Diaz
85 Broad Street
Charleston, SC 29401

JUDGE VANCE: The next case is *In Re: Cymbalta Products Liability Litigation*.

Mr. Wisner or Wisner?

MR. WISNER: It's Wisner. Good morning.

This Cymbalta litigation is growing very, very quickly. Presently there are 45 cases filed in 30 different jurisdictions across the country. And in those 45 cases, there are actually 60 different bundles of claims for different plaintiffs, married couples. That is just the tip of the iceberg. We presently, through the various attorneys that I've communicated with, we know that there are 1,800 cases that have been retained and are actively being investigated.

In addition to those, there are over 4,000 outstanding fee agreements that we sent to clients. So this is -- this is the beginning of a very, very large litigation.

JUDGE VANCE: Lilly takes the position that the common discovery has already taken place in the *Saavedra* action in which they've produced 1.8 million documents and conducted 30(b)(6) depositions, and that all you would have to do is export that discovery into these individual cases and that there is no more common discovery of Lilly that needs to be done. What is your response to that?

MR. WISNER: Well, one important clarification, the *Saavedra* case is a class action, but there has actually been

no substantive discovery that has been conducted. That is not part of one of the actions that have been noticed for this consolidation. The *Saavedra* personal injury cases also report to Judge Wilson in the Central District, specifically the *Herrera Hexum* cases. There has been a significant amount of discovery conducted in that case, but it has been done on a very, very short runway and there is a significant amount of discovery that still needs to occur.

JUDGE VANCE: What kind of discovery?

MR. WISNER: Well, currently -- actually, as we are speaking right now, depositions are being taken, but those depositions are being taken without guidance or input. This is being done in a very aggressive discovery schedule Judge King set out in those initial case Scheduling Orders that he issued.

For example, Your Honor, I'm not even counsel of record in that case and I haven't had the luxury of sitting down and parsing through all of that information the way that we would do in an MDL context. This idea that he's purported that there is essentially no disputed common issues of fact, it's just materially false. They have, at every turn, taken a position that the label of the Cymbalta drug is, in fact, sufficient. And we have, through expert discovery, have tried to show that that is not in fact true. That common issue applies to every single case involving Cymbalta. We

believe that we have the right and the obligation to our clients to do a thorough and full investigation of that discovery.

JUDGE KAPLAN: Can you explain to me briefly why it is you say that the label is insufficient?

MR. WISNER: Absolutely. The label currently says that the risk of withdrawal, suffering specific side effects is greater than or equal to 1 percent. We know based on all these studies that the risk of withdrawal is actually at least 45 percent, and our experts speculate and suspect that it could be upwards of 70 percent.

JUDGE VANCE: Isn't 1 percent, I mean, aren't those the same thing? 45 percent is greater than 1 percent.

MR. WISNER: Yes, but it also suggests that the risk is minimal. And this is important. I'm out of time. If I may respond?

JUDGE VANCE: Yeah, please do.

MR. WISNER: This is important because Cymbalta is a uniquely dangerous drug that comes through withdrawal. It has one of the shortest half-lives that exists out there; whereas Prozac, another Lilly product, has five or six days, Cymbalta is 12 hours. Without articulating or quantifying that risk of withdrawal, doctors reasonably think this is --

JUDGE KAPLAN: I'm sorry.

JUDGE RENDELL: Is this a matter of discovery of

fact or is this a battle of the experts?

MR. WISNER: It's both. One of the areas of discovery that we are trying to get into -- you see, Lilly actually pioneered the research on withdrawal. They did that when they were marketing Prozac in the nineties as a way to position Prozac as being the superior product.

JUDGE KAPLAN: Can I go back to your half-life after you're finished with your answer?

MR. WISNER: Sure. There is also some problems with the label, as well.

JUDGE KAPLAN: Doesn't the half-life comment go only to the question of how soon the withdrawal symptoms, if they are going to be experienced, manifest themselves?

MR. WISNER: Not entirely. There is two components to it. There is also an issue talking about regulation. But the half-life component, that is true, that helps signify how quickly an onset of withdrawal symptoms will be.

The second issue is also an area that has not been fully discovered in the context of the litigation at this point.

JUDGE KAPLAN: But I asked you about the label. I'm not sure I heard from you that the warning was inadequate with respect to speed of onset. And I don't see how it could be inadequate because it didn't say anything at all.

MR. WISNER: That's precisely the problem. Failure

to warn. If the label is going to --

JUDGE KAPLAN: So in other words, a pharmaceutical label has to say not only whatever is known about the likelihood of the side effect, but in addition, has to warn about how soon it will manifest, if the side effects manifest at all. Is that what you are saying?

MR. WISNER: No. There is a significant amount more. So there is a couple of issues. What we are alleging is they have to allege the severity, the frequency and the duration of the, more than likely in this case, side effect of the drug. They didn't do any of that. The only information it did provide was the very vague description of greater than or equal to 1 percent, which literally means between 1 and 100 percent, and that to us is fundamentally misleading. When we show this information to doctors, they gasp because this is something that is, without question, something that they --

JUDGE KAPLAN: That's true about your doctors but not the other side.

MR. WISNER: Fair enough.

JUDGE VANCE: I think we have our argument. Thank you.

MR. WISNER: One last point. I'm way over time, Judge.

JUDGE VANCE: You are over time.

MR. WISNER: Thank you, Your Honor.

MR. IMBROSCIO: May it please the Courts? Michael Imbroscio from Covington & Burling on behalf of Lilly.

This is a tough case. We had a number of cases on file and we have the promise that you heard this morning of many, many more. But I think this is also one of those cases, Your Honors, that what this Panel does will affect the size of the litigation. As soon as this Panel creates an MDL, there will be hundreds or thousands of cases because the enlargement cost of dumping these cases ends in zero.

What these cases are about essentially are individual facts of a particular plaintiff. And more importantly, the particular plaintiff's doctor. This is a very well-understood side effect that can occur with all antidepressants, including Cymbalta. We have a label that's very clear about it, in our view. And by the way, labels that in one of the earlier cases were found adequate as a matter of law.

JUDGE PROCTOR: Counsel, what steps have you taken with plaintiffs' counsel in both constituent groups to coordinate on common factual issues at this point?

MR. IMBROSCIO: Good question. The principal firm we have worked with has been the Pogust Braslow firm. They are the lawyers who have prosecuted every MDL that has come so far. The Baum Hedlund firm out in California has been

involved in the class action. It looks like they are going to get involved in the individual cases, but we have produced all the documents to Mr. Pogust and with the understanding he's going to share it with all of his -- all of --

JUDGE HUVELLE: Are you going to work on deposition protocols so you don't have to have multiple depositions of your --

MR. IMBROSCIO: Absolutely. We would do that. I mean, we've set it up, this has occurred already, can be applied in all of the cases. We have no qualms with that. In fact, that makes good sense.

JUDGE RENDELL: If there are 6,000 potential claimants, there is going to come a tipping point; is there not?

MR. IMBROSCIO: There might be, Your Honor. I guess the question is are we really going to litigate individual cases? I don't think that's going to happen because if you look at what we've done already, there has been six cases that have been litigated. The first case in Philadelphia was dismissed immediately. The second case was actually pending when the motion was filed, was dismissed within days of the plaintiff's deposition. Couldn't pursue the case.

Two cases we've got to summary judgment. The *Carnes* case before Judge Currie in South Carolina, where she put in

place, I think, a very reasonable plan: Let's depose the doctor, let's depose the plaintiff, see what the doctor says. The doctor said, Of course I knew about this. It's very understood in our general practice guidelines. We know this. She granted summary judgment.

Judge Sweet, he did the same thing in the *McDowell* case, the same thing, the expedited schedule, depose the doctor, and in that case the nurse practitioner who said, Of course I understand these issues. It's well understood.

JUDGE VANCE: Assuming that if we did centralize this -- and I'm not saying we are -- but what do you think about Minnesota?

MR. IMBROSCIO: Um, you know, it is in the middle of the country. I don't know if we looked carefully at that issue. I mean, what we really are concerned about is going back and forth to California. We would like to be somewhere closer to the East Coast, somewhere closer to Lilly. We have no position one way or the other in the District of Minnesota. I think, you know, if there is someone in mind, you know, we'll defer to the Panel's judgment.

Again, we don't think it should be, but we would not oppose it. As you know, our preference was not to be in California because it actually just costs a lot of money and takes a lot of time in these individual cases. I don't want to minimize it, but -- and in fact, there are some transient

effects of the vast majority of people and the cost of litigating these individual cases doesn't make sense from our perspective.

JUDGE KAPLAN: Does Lilly formally concede the general causation issue, that is, that the drug is capable of causing the effects. Does it concede the propensity, that is, the percentage of cases which occurs? Does it concede all of those things?

MR. IMBROSCIO: Cymbalta, like every medicine, in some cases can cause an issue. As to the frequency, that is a more complicated issue. The plaintiffs rely on a publically peer review article, trial article, which looks at the first set of trials. When you look at the entire clinical trial set which we produced, the percentage of them aren't so clear. It clearly happens and it clearly happened in one of the placebos, no doubt about that. But I don't think it's anywhere near what the plaintiffs suggested and it's very patient specific.

JUDGE KAPLAN: So there is going to be discovery and expert testimony as to the frequency of the effects?

MR. IMBROSCIO: Well, the answer, Judge, it's largely going to be a battle of the experts, in a sense. The discovery, the clinical trial data, which is going to make this up, what does the clinical trial show, that has already already all been produced. I think there has been 30, 35

clinical trials involving the lawsuit with Cymbalta. That's been done. I expect they are going to want to take depositions of company employees perhaps. But again, it's really going to be what does the clinical trial say? What does the data say? That is what it is. It's going to be an expert battle.

JUDGE KAPLAN: Is that true also of onset and duration?

MR. IMBROSCIO: Yeah, I think that's right. The clinical trials track these issues. I think in the end the use of the medicine is very patient specific, it's case by case, trial by trial. Some of these medicines work well for people but not other people. Conversely, some of these medicines lead to these issues on some people but not other people. It's very case specific. And I think that drives our litigation.

JUDGE RENDELL: If we do centralize, should we centralize the data along with it or not?

MR. IMBROSCIO: That's a hard question. As Mr. Wisner said, there has been no real discovery. Judge Wilson sort of jumped right into -- which I think made sense -- he's got class certification pending, it's been pending for a while. You know, I would be loath to say --

JUDGE RENDELL: What is their cutoff? Two weeks, isn't it?

MR. IMBROSCIO: Those are the individual cases. That's -- I actually -- we tend to agree those should not be centralized. We have a trial date in those cases and we are ready. Pretty much expert discovery we are doing this week and next.

So those cases, no. The individual *Herrara* cases no. It's a hard call. I guess I would want to defer to Judge Wilson. He's ready to send his opinion out in class certification. I'm not sure it makes total sense, but if he hasn't started writing it yet, if he said to the plaintiffs he doesn't want an MDL that involves Cymbalta, I would defer to your Panel and consultation with Judge Wilson on that.

JUDGE VANCE: Thank you.

MR. WISNER: Your Honor, I reserved a minute for rebuttal, but I clearly used that minute. If I could just quickly respond to --

JUDGE VANCE: Sure.

MR. WISNER: I think counsel points out the crux of the problem. Discovery has not been ordered. They have not agreed to depositions to just occur one time. They have not given us access to all the documents. That has not occurred. They have fought us at every point and prevented that from occurring. And this idea that litigating just 60 cases that are currently there independently and voluntarily is not going to happen. Unless we have a single judge who is

actually looking at the issues, this is going to spiral out of control quickly.

And I guess the last point is the *Saavedra* action, the class action, Judge Wilson indicated when he told us he did not want the MDL, he also planned to issue an order in 10 days. And that was on November 4th. So I believe --

JUDGE PROCTOR: That's judge time. That's like the last two minutes of the football game, it takes longer.

MR. WISNER: I anticipate getting the Order any time soon. I think having the *Saavedra* included in any centralization would be bizarre because it's a class action, it's consumer fraud cases and purely economic injuries.

Thank you.

JUDGE VANCE: Thank you.

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I certify that the foregoing is a correct transcript from the record of proceedings in the above-titled matter.

Amy C. Diaz, RPR, CRR December 7, 2014

S/ Amy Diaz